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ACCEPTANCE TESTING AND QA OF INTERVENTIONAL CARDIOLOGY SYSTEMS

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Interventional cardiology (IC) is a rapidly growing field of medical specialisation. Such procedures are complex and may subject patients and operators to higher levels of risk than those encountered in general radiology. Acceptance testing and quality assurance (QA) of radiological equipment, including IC equipment, is a requirement of the EU Medical Exposures Directive (MED) (97/43/EURATOM). In addition, the MED identifies interventional radiology as an area of special concern. This study presents the results of a survey of 17 IC systems (including several flat panel detector systems) in Irish hospitals. The results of the survey indicate large differences in patient doses between manufacturers for equivalent levels of measured image quality. In addition, all systems were found to have failed one or more acceptance tests, with 60% of systems demonstrating significant problems at acceptance testing. The results of the survey demonstrate the importance of acceptance testing and QA in IC. The results also provide baseline data, which may be used in the development of future QA guidelines.

INTRODUCTION

Interventional cardiology (IC) is a rapidly growing field of medical specialisation. This growth has been facilitated by advances in imaging technology and the development of increasingly sophisticated radiological equipment, among other factors.[1,2]

Such procedures are complex and may involve prolonged irradiations, which may subject patients and operators to higher levels of risk than those encountered in general radiology.[2–6,8] Radiation injuries from interventional cardiac procedures have been reported in the literature,[2–6] and international bodies have issued special advice in the area of interventional radiology. The Eu Medical Exposures Directive 97/43/EURATOM identifies interventional radiology as an area of special concern.[8] It also stipulates that acceptance testing and quality assurance (QA) of radiology equipment is mandatory.[8]

MATERIALS AND METHODS

An acceptance testing and QA survey of 14 interventional cardiac systems (17 imaging chains in total) were performed by the Department of Medical Physics and Bioengineering, St James's Hospital, Dublin. The systems tested are listed in Table 1 and included two flat panel digital detectors (FPDs). All image intensifier-based systems had a nominal detector diameter of 23 cm. The FPDs had field sizes of 20 cm $\times$ 20 cm and a diagonal diameter of 25 cm. This study was a continuation of a study previously published by the authors.[9] Seven systems were acceptance tested, four were approximately 6 y old and 3 were >10 y old.

Detailed acceptance testing and QA protocols were developed on the basis of published national and international guidelines.[10–21] The tests performed included an assessment of the following parameters:

- tube and generator performance
- radiation output
- half value layer
- detector entrance dose rates under automatic exposure control (AEC) in fluoroscopy and digital acquisition modes
- patient entrance dose rates under AEC in fluoroscopy and digital acquisition modes
- subjective assessment of image quality in fluoroscopy and digital acquisition modes; this included assessing limiting spatial resolution and threshold contrast detail detectability and was assessed using the Leeds test objects
- congruence of radiation and imaged fields
- dose area product (DAP) meter calibration
- radiation protection including radiation scatter and leakage measurements
- electrical safety (acceptance testing only)
- mechanical safety
- equipment condition

Tests were performed using calibrated ionisation chambers from Radcal Corporation Inc. and other calibrated test equipment.

RESULTS

The majority of the systems tested had a wide range of user selectable options available, including various pulsed fluoroscopy modes, digital acquisition frame rates, AEC curves and spectral filtration.

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Table 1. Systems tested.

No.	Type
1	Philips Integris Allura (bi-plane)
1	Philips Integris
2	Philips DCI
4	Siemens Coroskop
1	Siemens Axiom Artis
2	Siemens Bicor (bi-plane)
1	Siemens Axiom Artic Flat Panel
1	GE Advantx
1	GE Innova 2000

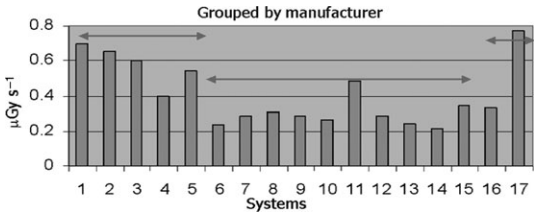

Figure 1. Detector entrance dose rates in the fluoroscopy mode grouped by the manufacturer.

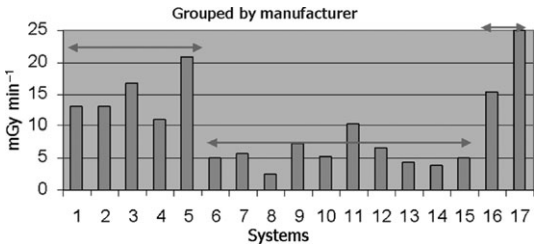

Figure 2. Patient entrance dose rates in the fluoroscopy mode grouped by the manufacturer.

Fluoroscopy

The pulsed fluoroscopy mode most frequently used on the equipment tested was 12.5 or 15 pulses per second (pps). The measured detector entrance dose rates on the 12.5/15 pps setting are presented in Figure 1.

The results were grouped by the manufacturer. Systems 4 and 5 had no pulsed fluoroscopy option available and system 11 was configured incorrectly (the 12.5 pps option was operating at 25 pps). Systems 15 and 17 are FPDS. Patient entrance dose rates[18] are presented in Figure 2.

These results (Figures 1 and 2) were made in the standard fluoroscopy mode. Measurements were also made in the 'high fluoroscopy' mode.

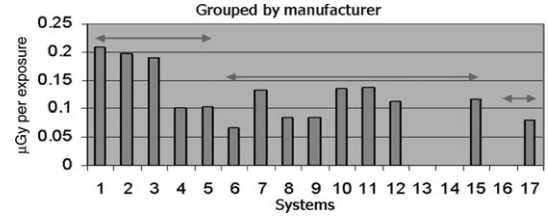

Figure 3. Detector entrance dose per exposure in the digital acquisition mode grouped by the manufacturer.

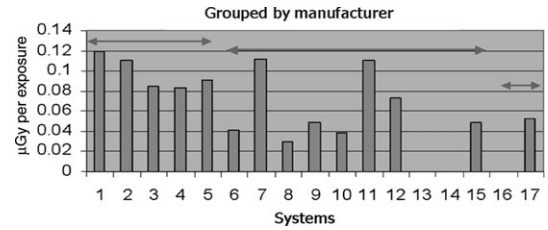

Figure 4. Patient entrance dose per exposure in the digital acquisition mode grouped by the manufacturer.

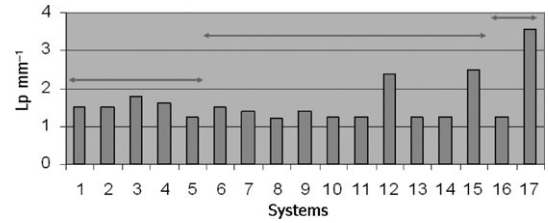

Figure 5. Spatial resolution in the fluoroscopy mode grouped by the manufacturer.

Digital Acquisition

Detector entrance dose per exposure and patient entrance dose per exposure in the digital acquisition modes are presented in Figures 3 and 4.

Image Quality

Subjective image quality tests were made in the fluoroscopy and digital acquisition modes using the Leeds test objects.[12–17] Figure 5 shows limiting spatial resolution results for the fluoroscopy mode. The threshold contrast in the fluoroscopy mode is presented in Figure 6. As stated earlier, systems 15 and 17 are FPDs. Threshold contrast detail detectability curves in the digital acquisition mode are plotted against a system in good adjustment shown in Figure 7.

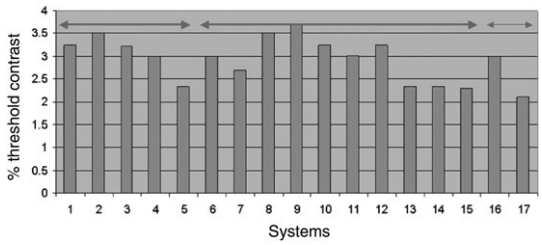

Figure 6. Threshold contrast in the fluoroscopy mode grouped by manufacturer.

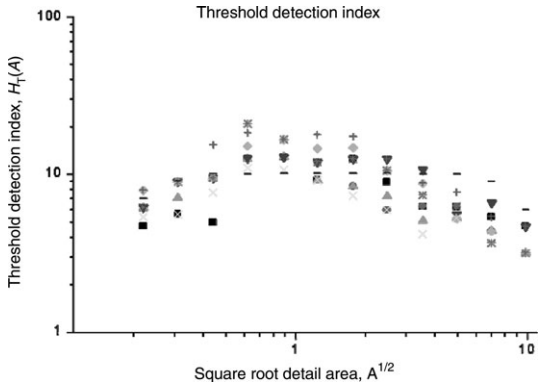

Figure 7. Threshold contrast detail detectability in the digital acquisition mode.

DISCUSSION

In terms of the measurements made, it was found that there was a wide range of user selectable dose rates available in the fluoroscopy and digital acquisition modes on many of the systems tested. On some systems, the selected mode is not prominently displayed to the operator although the difference in dose delivered from one mode to another may be quite substantial. The default configurations were not consistent and 20% of systems automatically defaulted to the 'high' mode of operation in fluoroscopy mode.

The detector entrance dose rates measured in the fluoroscopy mode demonstrated a significant variation across the systems tested for the same measurement set-up. The results ranged from 0.2 to 0.77 μGy s^{-1}. It is evident from Figure 1 that dose rates are manufacturer dependent, with a substantial difference between manufacturers. The measurements from one manufacturer's systems were consistently in the order of $>$100% than those from another manufacturer. An upward trend was also evident for new systems and for some FPDs.

Patient entrance dose rates measured in the fluoroscopy mode demonstrated a similar pattern ranging from 2.5 to 25 mGy min^{-1} for the same measurement set-up. Again, it is evident from Figure 2 that the results were manufacturer dependent, with a substantial difference evident between manufacturers.

It was also noted in the fluoroscopy mode that the dose rates classified as 'high' by one manufacturer were equivalent to those classified as 'normal' by another.

In the digital acquisition mode, the detector entrance dose per exposure ranged from 0.06 to 0.2 μGy per exposure for the systems tested. The patient entrance dose per exposure in the digital acquisition mode varied from 0.03 to 0.12 mGy per exposure. Again, the substantial difference across manufacturers was evident.

The results of the subjective image quality evaluation indicated that there was no overall improvement in image quality for higher dose systems in fluoroscopy or digital acquisition modes. Higher spatial resolution however was evident on the FPD systems (systems 15 and 17).

In terms of acceptance testing, problems or faults were encountered on all systems, with up to 60% of systems demonstrating significant faults or problems. This finding is consistent with the results of previous studies.[22] Problems included incorrect equipment configurations, electrical safety faults and non-delivery of required items. In addition, in the majority of cases, the DAP meters were found not to be calibrated to the systems at acceptance testing. The attenuation of the X-ray table and/or the spectral filtration of the system was not taken into account.

CONCLUSION

The results of this study demonstrate large dose variations in fluoroscopy and digital acquisition modes across the systems tested. The dose rates were found to be manufacturer dependent, with no improvements in image quality evident for the high-dose systems using the standard subjective image quality Leeds test objects. These findings are consistent with the findings of the previous study.[9]

Problems were identified with all radiological systems commissioned, with $\sim$60% of systems demonstrating significant problems. This is also consistent with previous findings[22] and emphasises the importance of performing QA and acceptance testing of IC systems, particularly given the higher levels of risk involved. The importance of including electrical safety testing in an acceptance testing programme is also evident from the study.

The results of this study may act as reference material for future cardiac QA guidelines.

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