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Impact of latest generation cardiac interventional X-ray equipment on patient image quality and radiation dose for trans-catheter aortic valve implantations

Short Title: TAVI image quality and radiation dose assessment of a new X-ray system

Full Paper

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Abstract

Objectives: This study aimed to determine the impact on radiation dose and image quality of a new cardiac interventional X-ray system for trans-catheter aortic valve implantation (TAVI) patients compared to the previously-used cardiac X-ray system.

Methods: Patient dose and image data were retrospectively collected from a Philips AlluraClarity (new) and Siemens Axion Artis (reference) X-ray system. Patient dose area product (DAP) and fluoroscopy duration of 41 patient cases from each X-ray system were compared using a Wilcoxon test. Ten patient aortograms from each X-ray system were scored by 32 observers on a continuous scale to assess the clinical image quality at the given phase of the TAVI procedure. Scores were dichotomised by acceptability and analysed using a Chi-squared test.

Results: Significant reductions in patient dose ($p<<0.001$) were found for the new system with no significant change in fluoroscopy duration ($p=0.052$); procedure DAP reduced by 55%, fluoroscopy DAP by 48% and "cine" acquisition DAP by 61%. There was no significant difference between image quality scores of the two X-ray systems ($p=0.06$).

Conclusions: The new cardiac X-ray system demonstrated a very significant reduction in patient dose with no loss of clinical image quality.

Advances in Knowledge: The huge growth of TAVI may impact on the radiation exposure of cardiac patients and particularly on operators including anaesthetists; cumulative exposure of interventional cardiologists performing high volume TAVI over 30-40 years may be harmful. The Phillips Clarity upgrade including improved image enhancement and optimised X-ray settings significantly reduced radiation without reducing clinically acceptable image quality.

Introduction

Trans-catheter aortic valve implantation (TAVI) is a treatment for patients with symptomatic aortic stenosis, who are high risk for conventional surgical aortic valve replacement. Cardiac interventional X-ray imaging systems allow for visualization of moving anatomy and interventional equipment in real time – which is essential for TAVI. High-quality contrast enhanced image sequences are captured in acquisition mode for diagnosis and treatment checks, using an iodine-based agent delivered through a catheter. Neither the native valve nor the aorta can be visualised without contrast agent. The contrast injections are also required to assess valve competence; a leaking or incompetent valve may require repositioning or further expansion. Fluoroscopy mode uses a lower quality X-ray imaging technique to aid cardiologists to navigate through the anatomy, and to guide valve positioning and deployment.

During TAVI, X-ray image quality must be sufficient to enable visualisation of individual struts of the prostheses and their relation to the patient anatomy. Some second generation valves have specific locking and release mechanisms as shown in Figure 1. Very high spatial resolution is required in order for interventional cardiologists to visualize these TAVI-specific details. Image frames within a sequence must be acquired at high enough rates to enable temporal resolution that is required for a given phase of the procedure. Image quality is related to the amount of radiation used to capture the image. For a quantum limited X-ray system the signal to noise ratio (SNR), a technical measurement of image quality, is proportional to the square root of the X-ray dose used to create the image (1); to double the SNR, the dose must be increased by four times.

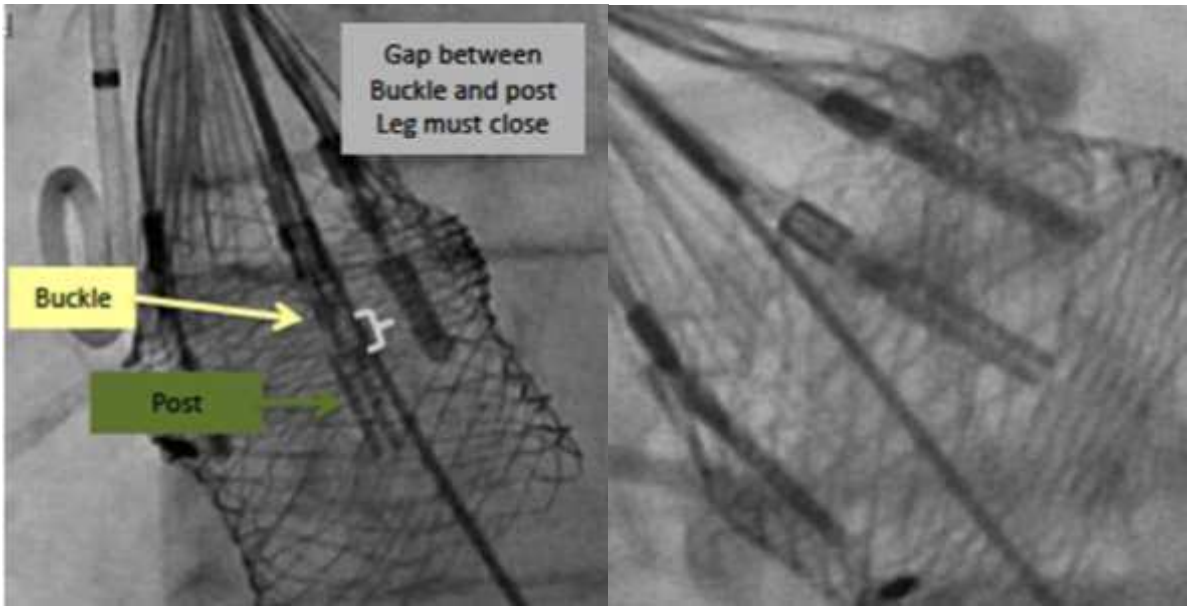

Figure 1. Left: small gap between buckle and post is seen; valve cannot be released because it is not locked. Right: no gap between buckle and post: valve can be released because it is locked

Exposure to X-rays can be harmful, and radiation doses from cardiac interventional procedures are the highest of any routine medical procedure (2,3). Those from TAVI are reportedly the highest of the interventional procedure radiation doses (4). Two types of biological damage may occur from radiation exposure. Deterministic effects include anatomic damage known to occur when radiation dose exceeds a specific amount, such as skin burns and hair loss on cardiac interventional patients (5–7) and cataracts to the eye lens on interventional cardiologists (8); recently the cataracts threshold dose was reduced by 75% (9), prompting efforts to reduce radiation doses to the eye (10). Stochastic effects, including damage to the DNA which may cause long term genetic defects and cancers, increase with radiation exposure; there is no specific threshold dose and risk is cumulative, so several decades may pass before manifestation (11).

Continuous evolution of TAVI technology and world-wide acceptance of the efficacy of the procedure (12–14) have translated to more procedures in all subsets of patients. In the UK

the first TAVI case was performed in 2007 with 66 additional procedures in 4 centres in that year, whereas in 2014 there were 1860 cases performed in 34 centres (15). Furthermore increasingly complex cases are undertaken with the use of alternative access routes, second generation valves, cerebral protection devices and 'valve in valve' for failed surgical bio-prostheses now becoming standard practice. An ageing population with a high prevalence of aortic stenosis, many of whom are unsuitable for open surgery, suggests that use of TAVI will continue to increase. In Germany TAVI has now overtaken surgical valve replacement as the most frequently used treatment for aortic stenosis (16).

Cardiac X-ray system settings should therefore be optimized to minimize radiation dose, whilst maintaining the required level of image quality for the specific patient size and clinical task, as enforced by the 'As Low As Reasonably Practicable' (ALARP) principle. It has been suggested, specifically for cardiac X-ray imaging, that image quality is at times higher than is required for the clinical task (17–19), causing unnecessarily high levels of radiation dose to both patients and personnel. In 2018 new legal requirements for lower radiation exposure limits will be implemented in the UK/EU via a new radiation protection directive (20).

Recent studies indicate that digital image enhancement has the potential to help allow for lower radiation doses to be used for TAVI procedures (21–25). The role of image enhancement has played an increasingly significant role in diagnostic radiology in the last decade; in real-time cardiac X-ray imaging, increased computing power is particularly beneficial, as more complex, adaptive (to image content) enhancement algorithms can be implemented in clinical practice. Each manufacturer has its own unique algorithms which enhance images in real-time, with task-specific enhancement allowing for visualisation of clinically-relevant anatomy.

Philips Healthcare's most recent interventional X-ray system, AlluraClarity (Philips Healthcare, The Netherlands) has ClarityIQ image enhancement with real-time image noise reduction algorithms which, in combination with anatomy-specific X-ray optimisation, promise to reduce patient dose (26). With this option, both the radiographic settings used to capture images, and the computer image processing applied to the images, are different to the previous generation equipment by the manufacturer. This system has allowed for reduced dose in neuroradiology (27,28) and other digital subtraction angiography (DSA) applications (29), percutaneous coronary interventional (PCI) (21–23,30) and electrophysiology (EP) procedures (25). The reduction in dose in TAVI procedures and, moreover an investigation of corresponding changes in clinical image quality for TAVI patients, has yet to be published. Such a comprehensive assessment of both radiation dose and image quality is crucial in establishing a thorough understanding of the clinical impact of a new X-ray system for this particular clinical application.

An AlluraClarity (hereafter Clarity) system was installed at Yorkshire Heart Centre, Leeds, UK, where six cardiac catheter labs are in clinical operation. The Clarity lab immediately became the preferred lab for TAVI procedures due to the manufacturer's claims of lower doses from this new X-ray system; initial procedure dose area product (DAP) observations seemed lower than were reported in the previously preferred lab for TAVI procedures. For this reason, as well as the rise in number of TAVI procedures at Yorkshire Heart Centre, TAVI procedures were investigated. There were 142 TAVI procedures in 2014 at Yorkshire Heart Centre, more than at any other UK hospital (15). This study's primary aims were to investigate if the Clarity system did indeed reduce X-ray dose to patients in TAVI, and if the image quality remained at a clinically acceptable level for TAVI with respect to the previously preferred equipment. The

study's secondary aims were to assess the dose reduction in fluoroscopy and acquisition modes separately, and to investigate if there was any alteration in fluoroscopy duration.

Methods

There were two key components to this study - an assessment of radiation dose and an assessment of image quality. Both components were completed in two phases - a pilot experiment to provide data for power calculations and the main investigation. Two of the six cardiac catheter labs in Yorkshire Heart Centre were included in the study – the new Philips AlluraClarity FD10 lab which commenced use in January 2014 and an Axiom Artis (Siemens Healthcare, Erlangen, Germany) which had been in use since 2007, as the reference lab for comparison. Details on the novel Philips Clarity settings can be found in manufacturer-provided documentation available on the company website (31).

This observational study collected data from computer records of patient doses from the hospital information technology systems, and as reported by the imaging systems; images were collected from the PACS system. Practitioners were not aware of the study and so performed the implantation as per typical practice. Both labs were generally fully booked for clinical use. All data were anonymised by removing personally identifiable information.

Radiation Dose

Procedure DAPs from 58 TAVI procedures completed in the reference lab were used to power the main dose study for a 30% difference in procedure DAP with 90% power and 5% significance.

Total procedure DAP as well as acquisition and fluoroscopy DAP and fluoroscopy duration were recorded for 41 TAVI patients from each lab; for the new lab data was obtained from the first six months of 2014, and for the reference lab data was obtained from the last six

months of 2013 (before the procedures moved to the new lab). Median values from the two labs were compared using a Wilcoxon test.

Image Quality

Image sequences from randomly-selected TAVI patient procedures from the new and reference labs were collected and DICOM headers were extracted for relevant metadata. Aortograms from each lab were randomly selected from this database until ten which included all stages of the TAVI implant (set up shots, partial deployment, full deployment) were collected. Image sequences were acquired at 15 frames per second; only one was chosen from any given patient. The body mass indices (BMI) of the patients ranged from 20 to 40 kg m^{-2} with a median of 27 kg m^{-2} for the reference lab and 24 to 33 kg m^{-2} with a median of 26 kg m^{-2} for the new lab. Contrast volume per aortogram was always 15 - 20 mL at 20 mL per second using a power injector.

The two groups of aortograms were scored on a continuous scale in a blind observer study. The two end points were “unsatisfactory” [0] and “exceeds requirements” [1] with mid-point “acceptable” [0.5]. Observers were asked to focus on overall level of diagnostic image quality, answering the question “How good is the quality of the image for assessing the aortic stenosis or other clinically relevant image data at this phase of the procedure?” by clicking anywhere on the continuous scale as shown in Figure 2. The use of a continuous scale allowed for flexibility in the observer’s response and helped avoid issues associated with ordinal scales (32). All aortograms were 512 by 512 pixels at 8 bit depth, displayed at 15 frames per second. Bespoke software with a graphical user interface was designed in MATLAB 2013b (The Mathworks Inc, Natick, USA) specifically to execute this observer study. The aortograms were shown to observers in a random order, which differed for each observer, and they looped

continuously until the observer clicked on the scale; then the next aortogram was shown, with no time limits imposed. Ratings for each aortogram were automatically translated into quantitative scores between zero and one for statistical analysis; these quantities were not shown to observers.

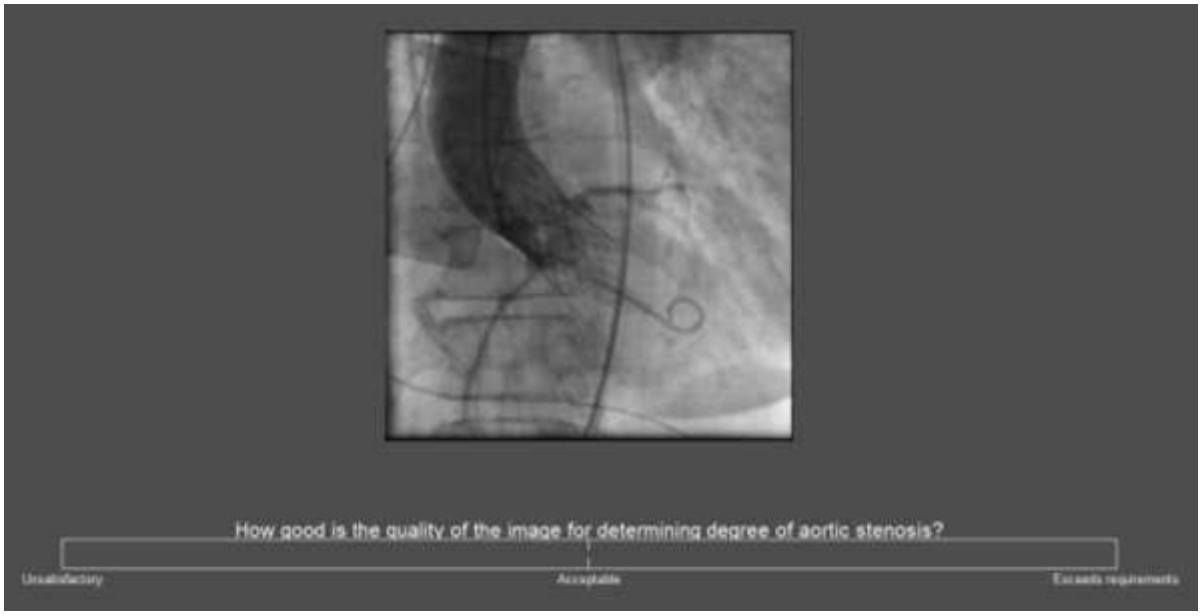

Figure 2. Screenshot of graphical user interface used for this study

A pilot study was conducted to power the image quality study for a 30% difference in image quality with 80% power and 5% significance; three medical imaging experts with 8, 20 and 25 years' experience with cardiac X-ray imaging scored the aortograms as described above. A RadiForce RX340 medical grade monitor (EIZO Corporation, Ishikawa, Japan) was used, approximately 70 cm away from the observer, in a room with slightly dimmed lighting (as in a radiology reporting room).

The main study was approved by the University of Leeds Research Ethics Committee; recruitment took place in Leeds and Nottingham NHS Trust Hospitals and the British Cardiovascular Society (33) annual cardiology meeting exhibition hall. Clinical professionals with relevant experience with TAVI images were recruited. Observers were informed of the

purpose of the study, provided with a participant information sheet, and signed a participant consent form; the forms were not linked to results, hence the data were anonymous. The observers provided only their clinical profession and number of years' experience. Observers then each assigned scores to the twenty images as described above, using a Eonis MDRC-2224 BL clinical display unit (Barco, Brussels, Belgium); Leeds participants used a Radiforce RX340 monitor.

The statistical analysis was performed using the statistical software R (R Foundation for Statistical Computing, Vienna, Austria). The observer scores were dichotomised by acceptability, with scores of 0.5 or higher classed as acceptable; binary scores were then analysed using a chi-squared test. A Pearson's Chi-squared test was used to determine whether the clinical specialist status of the observers impacted on the acceptability ratings. The clinical professionals who took part in the study were classed as either TAVI specialist or non-specialist according to whether they contribute to clinical image reporting.

Results

Radiation Dose

The power calculation showed that a minimum of 17 cases from each group would be required for the radiation dose component of the study; the 41 that were used were in excess of this minimum requirement. Box plots are shown in Figures 3 and 4 for DAP and fluoroscopy duration respectively. Median total patient procedure doses were 4031 and 8930 cGy cm^2 from the new and reference labs respectively, showing the new lab to be 55% lower. Median acquisition DAPs were 785 and 2029 cGy cm^2 from the new and reference labs respectively, showing 61% reduction in the new lab. Fluoroscopy median DAPs were 3460 and 6588 cGy cm^2 from the new and reference labs respectively, showing 48% reduction in the new lab. The Wilcoxon test showed strong statistically significant differences in medians for both

fluoroscopy and acquisition patient doses at the 5% significance level ($p << 10^{-5}$ in both cases). Median fluoroscopy durations were 19:09 (min:sec) and 22:30 for the new and reference labs respectively, showing no statistically significant difference ($p = 0.052$) between the two labs.

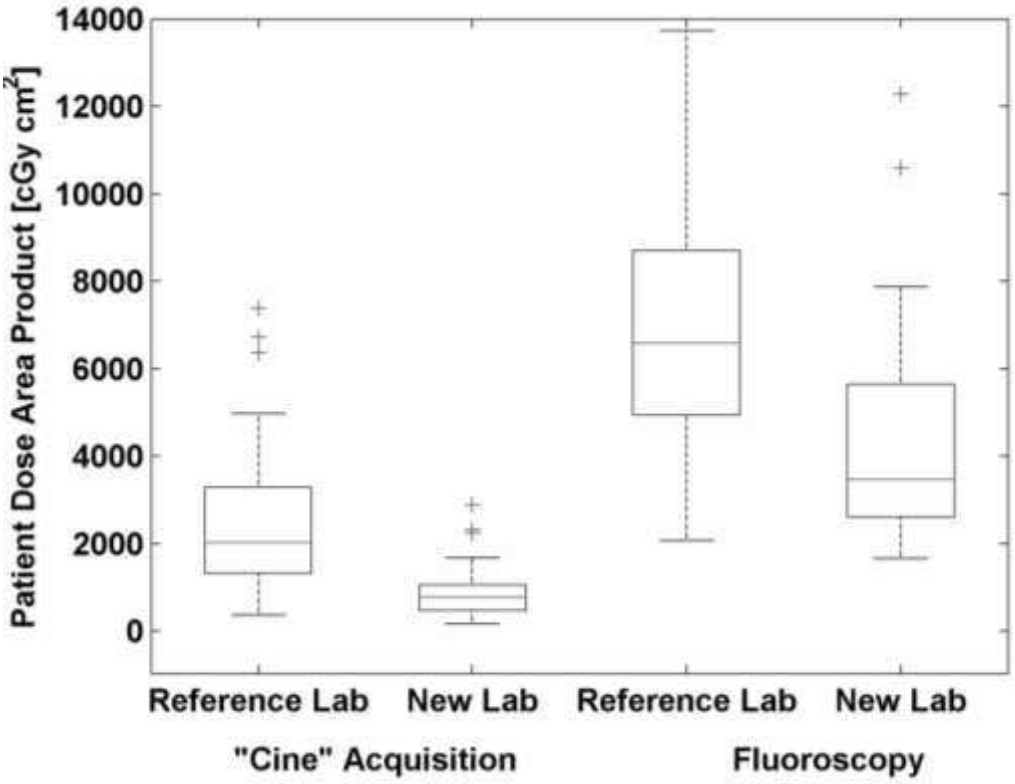

Figure 3. Box plots of acquisition and fluoroscopy dose

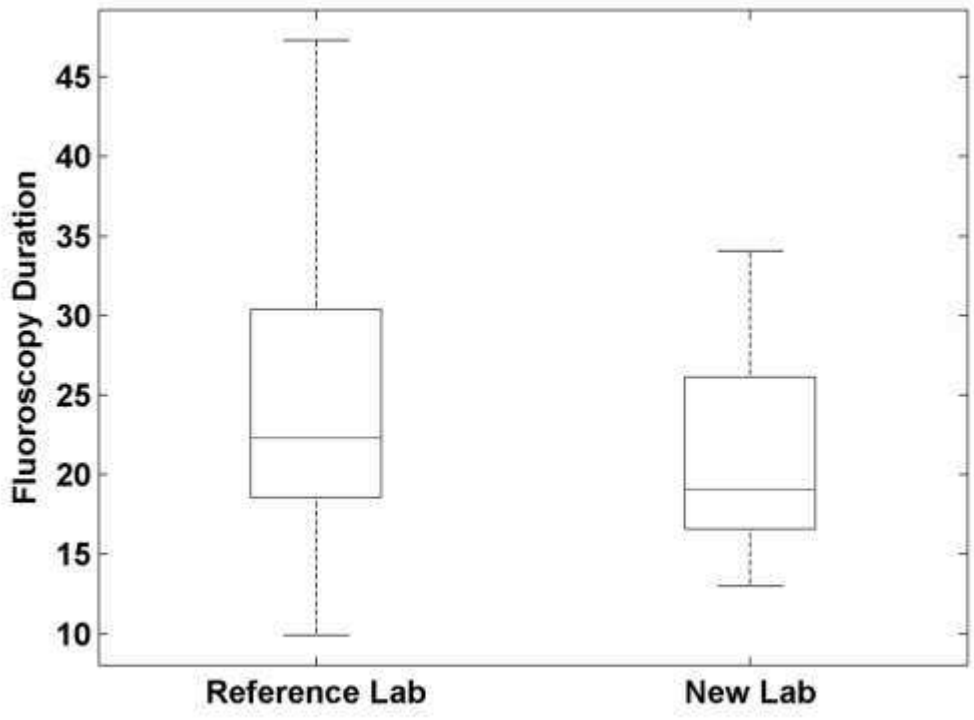

Figure 4. Box plot of fluoroscopy duration

Image Quality

The pilot study showed that a minimum of 28 observers were required for the main image quality study; 32 observers participated in the study. There were six cardiologists, three radiologists, seven radiographers, six medical students training in radiology or cardiology, three medical physicists and seven clinical support staff. Their experience ranged from 0-35 years, with a mean of 9.4 years. Half of the observers were classed as TAVI specialists and half non-specialists.

Box plots of the image quality scores are shown in Figure 5; scores covered the entire range 0-1 when rounded to one decimal point, and 72% were classed as acceptable. Median scores for the new and reference labs were 0.56 and 0.60 respectively. The Chi-squared test showed no significant difference between acceptability scores in the two labs ($p=0.06$). The Pearson's

Chi-squared showed no significant difference between the image quality scores of the specialist and non-specialist observer groups in terms of acceptability (p=0.87).

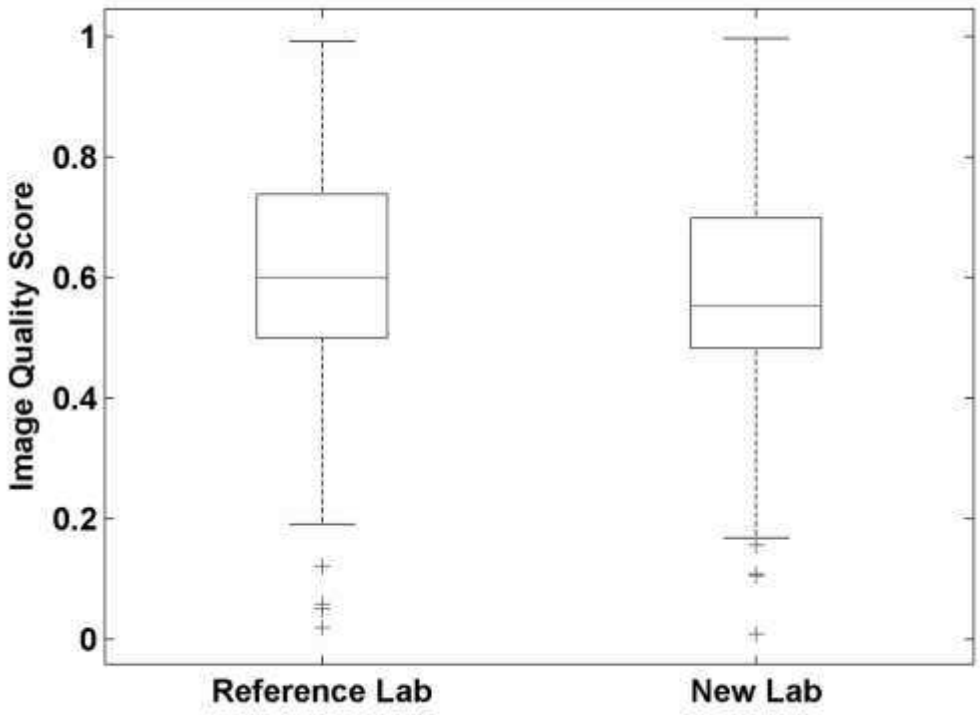

Figure 5. Box plots of image quality score

Discussion

Given the advantages associated with the reduced dose from the newer imaging equipment it is encouraging to see that the absolute difference in image quality scores was very small (0.04); this difference was not significant at the 5% level although it was close to the p-value threshold. Both the dose and image quality components of the study were strengthened by statistically planning, i.e. pilot studies and power calculations.

Since TAVI procedures are relatively new and increasing in frequency, there are relatively few interventional cardiologists who specialize in this field compared to, for example, PCI. Therefore, in order to recruit the large number of observers required for 80% power in the image quality study (28), other clinical professionals aside from interventional cardiologists were recruited - those who had worked on or observed a number of TAVI cases and understood the phase of the implant during which each aortogram was acquired. Half of the observers did not take part in image reporting as part of their clinical profession, however their acceptability ratings of the images were not significantly different to the specialist observers. This demonstrates that, although recruiting these additional observers is not ideal, it did not affect the outcome of this study. Moreover, the large amount of observers who took part in the study (32)) represented a broad range of institutions across the country and therefore a range of local philosophies on what makes a good cardiac image. This was beneficial because the observers were not, as a group, accustomed to one particular X-ray system more than another.

These results are important for interventional cardiologists who perform TAVI procedures; changes in X-ray settings which allow for lower reported DAPs will also allow for lower radiation exposures to personnel (34). Concern for damaging effects of radiation from interventional cardiac procedures is typically directed at patients (35), however impact on cardiologists is not as often addressed (36). Eye lens cataracts are common and stochastic effects from radiation are also becoming a concern for interventional cardiologists. Cumulative radiation exposure from a working lifetime has been reportedly high enough to increase the cardiologist's risk of cancer to 51% (37,38) from the baseline risk of 25%. Brain and neck tumours in interventional cardiologists may be induced by occupational radiation

exposure (39,40). Cardiologists may begin clinical practice as young as their early thirties (41), increasing the risk of cancer during their lifetime. Women are at slightly higher risk than men (11), and the number of female cardiologists is rising (41). The Organization for Occupational Radiation Safety in Interventional Fluoroscopy (ORSIF) was founded by an American cardiovascular surgeon who pioneered the endovascular approach to surgery, to increase awareness of this issue; he believed his bilateral lens implants in both eyes, calcified carotid artery and brain tumour were a result of being chronically exposed to ionising radiation whilst performing these image-guided patient procedures (42). A new initiative by the British Institute of Radiology (43) has responded by creating an online learning resource for interventional cardiologists. Later in 2016 it will be mandatory in the UK for them to learn more about the negative effects of radiation, as radiologists are expected to do.

This study compared two X-ray cardiac catheter laboratories very similar in design and operation. The X-ray system in the reference lab was biplane, a feature never used during TAVI, and the new lab had large monitors. Nonetheless, the differences in image quality and dose levels found are mainly from the X-ray imaging systems within the labs.

Fluoroscopy duration was compared to assure any changes in dose were from the difference in interventional labs, not from a difference in X-ray duration (for example due to a difference in case complexity between the two groups). The number of acquisition image frames was not accurately recorded and hence was not used; in the hospital database it was impossible to differentiate an acquisition sequence from a fluoroscopy sequence that was stored as per good radiological practice. Interventional cardiologists reported that the storage of fluoroscopy sequences increased after moving the TAVI procedures to the Clarity lab at Yorkshire Heart Centre.

Some of the image quality assessments took place in the exhibition hall of a conference, and therefore the ambient lighting was not dimmed as it would be in a radiology reporting room. However, dimmed lighting is not used in the local cardiac catheter labs, as reported to be the case elsewhere (44). Moreover, for each observer both sets of aortograms were viewed under the same lighting conditions, and therefore lighting was not a variable between the image sets.

There have been no past published studies which compared the Philips Clarity system to the Siemens Axiom Artis in terms of cardiac interventional patient dose and image quality. Any similar studies did not pertain to TAVI patients, therefore no comparison can be made. A summary of past studies which compared the Clarity with Allura Xper Philips Healthcare systems, for other clinical applications can be found in a previous publication (24).

Conclusion

The newly-installed AlluraClarity cardiac catheter lab had 55% lower total patient procedure dose area product (DAP) for trans-catheter aortic valve implantation (TAVI) patients than the reference lab, which was previously used for TAVI procedures. Fluoroscopy and digital image acquisition DAPs were 48% and 61% lower respectively, with no statistically significant difference in fluoroscopy duration between the two labs. Moreover, the clinical acceptability of the aortograms acquired on the Clarity system was not affected by the reduced dose.

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corresponding imaging system data. The authors would like to thank all the observers who contributed to the image quality assessment.

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Figure Legends

Figure 1. Left: small gap between buckle and post is seen; valve cannot be released because it is not locked. Right: no gap between buckle and post: valve can be released because it is locked

Figure 2. Screenshot of graphical user interface used for this study

Figure 3. Box plots of acquisition and fluoroscopy dose

Figure 4. Box plot of fluoroscopy duration

Figure 5. Box plots of image quality score