

Impact of New-generation Hybrid Imaging Technology on Radiation Dose during Percutaneous Coronary Interventions and Trans-femoral Aortic Valve Implantations: A comparison with conventional flat-plate angiography



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Background	Technological advancements in newer-generation catheterisation laboratories may reduce patient and occupational radiation exposure.
Methods	We compared fluoroscopy time and dose-area product (DAP) between a Philips Allura X-PER FD20 and Siemens Artis Zeego Hybrid systems for 47 single-vessel percutaneous coronary interventions (PCI) and 35 transcatheter aortic valve implantations (21 Corevalve, 14 Edwards Sapien TAVI) using the FD20, versus 30 PCI and 28 TAVI (15 Corevalve, 13 Sapien) with the Zeego over a 24-month period.
Results	Multivariate analysis revealed that, adjusting for patient weight and fluoroscopy time, DAP (median, interquartile range) was 26% lower for PCI with the Zeego than the FD20 [55.6 (27.0-91.5) vs 77.6 (51.2-129.1) Gy.cm ² , P=0.03] and using tomographic imaging with the Zeego did not increase DAP for TAVI procedures [98.1 (65.9-136.6) vs 112.4 (64.9-156.2) Gy.cm ² (P=NS)]. Although fluoroscopy times were longer for TAVI procedures than PCI with both systems (23.5-24.4 vs 7.3-9.2mins, p<0.0001), there was a significant difference in DAP between PCI and combined TAVI with the Zeego (55.6 vs 112.4 Gy.cm ² , P<0.006) but not with the FD20 (77.6 vs 98.1 Gy.cm ² , P=NS).
Conclusion	Specific dose-reducing features of the new-generation system reduced DAP more for PCI than TAVI, as valve replacement procedures use additional cine-acquisition not necessary for PCI.
Keywords	Radiation • Cardiac catheterisation • Percutaneous coronary intervention • Transcatheter aortic valve replacement • Coronary angiography • Structural heart intervention

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Introduction

Radiation exposure to staff and patients during cardiac imaging is a major concern, particularly in the cardiac catheterisation laboratory where sequential fluoroscopy and high-dose cine acquisition result in high radiation dosages [1]. Irrespective of the actual dose involved, the risk/benefit ratio to patients strongly favours continued use of diagnostic X-ray imaging techniques [2], and current radiation safety programs encourage reduction in medical radiation exposure by means of staff education, regular monitoring and recording of radiation dose for each procedure, mandatory licensing requirements, following ALARA (As Low As Reasonably Achievable) principles and monitoring personal dosimetry [3,4]. Nevertheless, radiation exposure in the cardiac catheterisation laboratory is unavoidable, and manufacturers have responded by developing new technology, instrumentation and software aimed at reducing radiation dosage during diagnostic and interventional imaging.

Increasing use of percutaneous treatment for structural heart interventions and for complex coronary artery disease continues to raise concerns regarding the radiation risk posed to patients and attendant healthcare staff, and recent studies have quantified doses generated during various cardiac interventions [5,6]. Reported levels of fluoroscopy time, dose area product (DAP) and air kerma represent the radiation risk associated with these procedures and may also indicate dosages expected from other structural heart interventions. These studies, however, used fluoroscopic equipment that has since been replaced by a new generation of angiography suites that can potentially improve radiation safety as the new technology becomes more widely distributed.

This study compares differences in case time, fluoroscopy time, dose area product and \pm air kerma for percutaneous coronary interventions (PCI) and two types of transcatheter aortic valve implantation (TAVI) between one of the new generation X-ray machines (Artis Zeego, Siemens, Munich) and a previous-generation flat-plate angiography model (Allura X-PER FD20, Philips, Amsterdam, The Netherlands) with flat-plate technology that is still in common use. Transcatheter aortic valve implantation patients received either a Corevalve (Medtronic Inc., Minnesota) or an Edwards Sapien valve (Edwards Lifesciences, Irvine, California).

Materials and Methods

Study Design

The cardiac catheterisation laboratory operates a Siemens Artis Zeego hybrid system installed in May 2013 and also uses a Philips Allura X-PER FD20 flat-plate angiography system in an adjoining suite. Four experienced interventional cardiologists routinely perform PCI in both suites, while TAVI and other structural heart studies are performed exclusively in the hybrid laboratory. The objective of this study was to determine how effective the new-generation angiography technology is

in reducing radiation risk by comparing radiation dose for all single-vessel PCI ('standard PCI'), as previously described [5], and for all TAVI procedures conducted with the Siemens Zeego and Philips FD20 during an overlapping 12-month period both before and after installation of the hybrid unit. As all staff routinely circulate between cases and change roles during any procedure, no attempt was made to relate radiation dose to personal dosimetry.

Patients and Procedures

A total of 140 patients were entered into the study. Mean age of 30 Zeego PCI patients (\pm 1SD) was 67.0 ± 10.4 years, mean weight (\pm 1SD) was 83.1 ± 15.7 Kg, and 80% were male. For 47 FD20 PCI patients mean age (\pm 1SD) was 72.3 ± 11.2 years, mean weight was 79.2 ± 15.6 Kg, and 79% were male. Mean age of 28 Zeego TAVI patients (\pm 1SD) was 86.0 ± 4.3 years, mean weight (\pm 1SD) was 71.4 ± 14.6 Kg, and 61% were male. For 35 FD20 TAVI patients, mean age (\pm 1SD) was 85.2 ± 7.0 years, mean weight (\pm 1SD) was 70.2 ± 15.8 Kg, and 49% were male. All patients undergoing percutaneous PCI or transfemoral TAVI (Corevalve or Sapien) over the two-year period were included in the analysis, subject to certain exclusion criteria. In keeping with previous definitions of 'standard' PCI (diagnostic coronary angiography in combination with single-vessel PCI) and to exclude potential bias with case complexity, only successful procedures were analysed and PCI cases involving coronary bypass grafts, chronic total occlusion, or additional procedures such as fractional flow reserve, intravascular ultrasound or rotational atherectomy were excluded. Percutaneous coronary intervention data for both radial and femoral approaches were combined for this study. Although there are reports that radial PCI results in increased DAP [7,8], this may be due to a learning curve or selection bias [9], and the difference is considered comparable or marginal in experienced hands and in high-volume centres [10–12].

Low-osmolar, non-ionic contrast medium (Ultravist-370, Schering Australia, Sydney) was used. Haemostasis was achieved by a Terumo radial TR band (Terumo Corporation, Tokyo), internal suture device (Perclose, Abbott Laboratories, California), collagen plug (Angio-Seal, St. Jude Medical, Minnesota), or manual compression. All TAVI were performed by femoral arterial puncture with additional lines in the radial or femoral arteries.

Instrumentation

Independent periodic quality assurance tests to ensure optimum performance and consistency of radiation output were conducted by accredited contractors for the Environmental Protection Agency (Gammasonics Radiological Services, Sydney, and X-Med, Sydney). The average input dose rate for the Philips FD20 unit was $115 \mu\text{Gy}/\text{min}$ for 15 cm field size, $109 \mu\text{Gy}/\text{min}$ for 22 cm field size, $79 \mu\text{Gy}/\text{min}$ for 31 cm field size and $53 \mu\text{Gy}/\text{min}$ for 48 cm field size. For the Siemens Zeego, the corresponding average input dose rates were $105 \mu\text{Gy}/\text{min}$ for 16 cm field size, $42 \mu\text{Gy}/\text{min}$ for 22 cm field size, $30 \mu\text{Gy}/\text{min}$ for 32 cm field size and

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