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ORIGINAL ARTICLE

# Radiation Dose During Percutaneous Treatment of Structural Heart Disease

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**Background** With the increased application of structural heart intervention techniques, there is concern over increasing radiation dose, especially during lengthy procedures.

**Methods** We compared data from 91 consecutive single-vessel percutaneous coronary interventions, 69 patent foramen ovale closures, 25 atrial septal defect closures, 49 percutaneous transluminal mitral valvuloplasties, 57 balloon aortic valvuloplasties, 53 trans-catheter aortic valve implantations (TAVI), 21 left atrial appendage occlusions and 7 MitraClip® procedures.

**Results** The following fluoroscopy times and dose-area product (median, interquartile range) were recorded: patent foramen ovale closure (7.8, 5.3-10.9 minutes; 16.9, 7.5-30.6 Gycm$^2$), atrial septal defect closure (10.1, 7.3-13 minutes; 15.5, 11.6-30.5 Gycm$^2$), percutaneous transluminal mitral valvuloplasty (14.3, 11.4-24.2 minutes; 37.4, 19.8-87.0 Gycm$^2$), balloon aortic valvuloplasty (8.4, 5.2-13.2 minutes; 19.8, 10.2-30.0 Gycm$^2$), Edwards Sapien™ TAVI (24.0, 19.3-34.4 minutes; 86.4, 64.0-111.4 Gycm$^2$), Medtronic CoreValve® TAVI (19.4, 15.0-26.0 minutes; 101.9, 52.6-143.2 Gycm$^2$), left atrial appendage occlusion (18.5, 15.7-29.1 minutes; 84.1, 36.4-140.0 Gycm$^2$), Mitraclip® procedures (37.2, 14.2-59.9 minutes; 89.1, 26.2-118.7 Gycm$^2$), coronary angiography and single vessel percutaneous coronary intervention (6.6, 5.1-11.0 minutes; 62.5, 37.0-95.8 Gycm$^2$).

**Conclusion** For structural heart interventions, dose-area product was not significantly greater than for coronary angiography with single-vessel percutaneous coronary artery intervention. This should be reassuring to patients and staff attending prolonged structural heart interventions.

**Keywords** Structural heart intervention • Radiation • Percutaneous coronary intervention • Transcatheter aortic valve • Percutaneous mitral valve intervention • Percutaneous left atrial appendage occlusion

## Introduction

Interventional cardiology has progressed to include the percutaneous correction of structural heart disease along with treatment of coronary artery disease. In recent years, an increasing number of centres have commenced structural heart intervention (SHI) programs worldwide. With the introduction of these newer SHI modalities, there is concern over increasing radiation exposure to both patients and staff, especially during lengthy procedures. Extended fluoroscopy and acquisition times for patients in prolonged interventional procedures can be associated with undesirable radiation-induced effects such as burns, depilation, dermal necrosis and future risk of malignancy [1]. This perceived increase in radiation risk is of particular concern to those who are young and in their fertile years [2]. We therefore compared differences in procedure time, fluoroscopy time and dose-area product (DAP) between single-vessel percutaneous coronary intervention (standard PCI) and various SHIs.

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# Methods

The interventional suite at St Vincent's Hospital, Sydney, consists of one public and two private cardiac catheterisation laboratories. Each laboratory houses a Philips single-plane Allura FD20® (Koninklijke Philips Electronics, The Netherlands) angiography unit that records DAP and exposure times. Procedure times were monitored with either a Philips Exper Xims® (Koninklijke Philips Electronics, The Netherlands) or a Siemens Cathcor system® (Siemens-Elema AB Electromedical Systems Division, Solna, Sweden).

## Inclusion and Exclusion Criteria

All patients who had SHI or PCI between July 1, 2008 and June 30, 2012 were included in the initial search. This four-year time span was selected to coincide with the introduction of percutaneous trans-catheter aortic valve implantation (TAVI) at the study site in 2008. Up to this time, SHI consisted only of percutaneous transluminal mitral valvuloplasty (PTMV), balloon aortic valvuloplasty (BAV), atrial septal defect (ASD) closure and patent foramen ovale (PFO) closure. Informed, written consent was obtained from each patient. All SHI in both public and private laboratories were performed by four senior consultant interventional cardiologists and these procedures were compared only with PCI performed by the same senior cardiologists in one of the suite's three cardiac catheterisation laboratories. Additional PCI undertaken by three other experienced consultant interventional cardiologists in the same unit during the same study period were used to establish and compare baseline values. PCI involving radial artery access and additional diagnostic evaluation such as intravascular ultrasound (IVUS), pressure wire analysis of fractional flow reserve (FFR), and complex additional interventions such as rotational arterectomy were excluded from comparison with SHI procedures. These ancillary diagnostic modalities were excluded because they were relatively infrequent in our practice at the time and to avoid potential bias in selecting the index PCI procedure used for comparison with SHI.

## PCI

Given that the ratio of total PCI to SHI during the entire study period was in the order of 10:1, we selected a representative number of consecutive successful PCI performed mid-way through the study period, rather than analysing every PCI conducted during the entire four year period. This was done in order to facilitate statistical comparison between thousands of PCI with the limited number of SHI over the specified timeframe and because including thousands more PCI was unlikely to affect the results obtained or to contribute any additional information.

In keeping with laboratory practice at our institution at the time, all PCI procedures were performed via femoral arterial puncture. Low-osmolar, non-ionic contrast medium (Ultravist-370®, Schering Australia, Sydney) was used. Haemostasis of the femoral artery was usually achieved by means of a closure device such as a collagen plug (Angio-Seal™, St. Jude Medical, Minnesota, USA) or internal suture device (Perclose®, Abbott Laboratories, California, USA).

## SHI

The SHI procedures performed during the study included PTMV, BAV, trans-septal closure of PFO and ASD, TAVI, occlusion of the left atrial appendage (LAA), and MitraClip® correction of severe mitral regurgitation. The same contrast medium was used for all procedures. Femoral arterial closure was also achieved by the same suture device, as indicated, while manual compression was applied for venous closure.

## The Index PCI Procedure

In order to compare radiation dose between different procedures performed by various operators in different angiography suites, it was considered necessary to first determine a standard basis for comparison. On the basis that diagnostic coronary angiography in combination with single-vessel PCI (''standard'' PCI) was the most common procedure performed in the cardiac catheterisation laboratories at our institution, and because this represented a ''reasonable'' level of radiation risk that was accepted by laboratory staff at a single sitting, this became the index procedure for comparison with SHI. The alternative, classifying each PCI according to various levels of complexity using current guidelines [3], was considered unnecessarily complex for our purposes, and potentially subjective.

Data from 385 consecutive successful coronary angiography and single-vessel PCI performed by the seven skilled consultant interventional cardiologists were categorised by operator and stent number, and analysed to establish baseline values. 220/385 cases were single-vessel PCI. Of these, 91 were performed by the four specialists performing both PCI and SHI. Data from these 91 single-vessel PCI were selected for comparison with all consecutive, successful SHI (49 PTMV, 57 BAV, 53 TAVI, 69 PFO closures, 25 ASD closures, 7 MitraClip® procedures and 21 left atrial appendage (LAA) closures). Pooled PCI and SHI data were also used to evaluate patient demographics for both cohorts.

## Instrumentation

All procedures were performed in the cardiac catheterisation laboratories and not in a hybrid surgical suite. TAVI patients all received either a Medtronic CoreValve® (Medtronic Inc, Minnesota, USA) or Edwards Sapien™ (Edwards Lifesciences, Irvine, California, USA) transcatheter aortic valve. The transfemoral approach was used for all TAVI patients included in this study. For PFO closure, an Amplatzer PFO Occluder™ (St Jude Medical, Minnesota, USA) device was used. LAA occlusion was achieved using a Watchman® device (Atritech Inc, Plymouth, Minnesota, USA). An Abbott MitraClip® system (Abbott Vascular, Illinois, USA) was used for patients undergoing percutaneous intervention for severe mitral regurgitation. PTMV, used in the treatment of severe mitral valve stenosis, was performed using an Inoue mitral valvuloplasty balloon (Toray Medical Co. Ltd, Chiba, Japan). BAV was performed using a NuCleus® aortic valvuloplasty