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Clinical and Procedural Characteristics Associated With Higher Radiation Exposure During Percutaneous Coronary Interventions and Coronary Angiography

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***Background*—**We aim to study the clinical and procedural characteristics associated with higher radiation exposure in patients undergoing percutaneous coronary interventions (PCIs) and coronary angiography.

***Methods and Results*—**Our present study included all coronary angiography and PCI procedures in 5 PCI centers in the Western part of Sweden, between January 1, 2008, and January 19, 2012. The radiation exposure and clinical data were collected prospectively in these 5 PCI centers in Sweden as part of the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). A prediction model was made for the radiation exposure (dose–area product) expressed in Gy·cm^2. A total of 20 669 procedures were included in the present study, consisting of 9850 PCI and 10 819 coronary angiography procedures. In multivariable analyses, body mass index (β=1.04; confidence interval [CI], 1.04–1.04; *P*<0.001); history of coronary artery bypass graft surgery (β=1.32; CI, 1.28–1.32; *P*<0.001); 2, 3, or 4 treated lesions (2 treated lesions: β=1.95; CI, 1.84–2.03; *P*<0.001; 3 treated lesions: β=2.34; CI, 2.16–2.53; *P*<0.001; and 4 treated lesions: β=2.83; CI, 2.53–3.16; *P*<0.001); and chronic total occlusion lesions (β=1.39; CI, 1.31–1.48; *P*<0.001) were associated with the highest radiation exposure. After adjusting for procedural complexity, radial access route was not associated with increased radiation exposure (β=1.00; CI, 0.98–1.03; *P*=0.67).

***Conclusions*—**In the largest study population to assess radiation exposure, we found that high body mass index, history of coronary artery bypass graft surgery, number of treated lesions, and chronic total occlusions were associated with the highest patient radiation exposure. Radial access site was not associated with higher radiation exposure when compared with femoral approach. **(*Circ Cardiovasc Interv*. 2013;6:501-506.)**

Key Words: fluoroscopy ■ percutaneous coronary intervention ■ radiation

Radiation dose reduction for percutaneous coronary intervention (PCI) is particularly important as procedures become more complex. This could potentially result in longer procedures and expose patients to an increased or a higher procedural related radiation. The International Commission on Radiological Protection[1] has described the risks of radiation exposure from fluoroscopy-guided procedures. They reported an increase of radiation-induced injuries in patients' skin (deterministic effect) and an increase of the risk to develop radiation-induced cancers (stochastic effect).

Therefore, it is of utmost importance to study the factors that are associated with increased radiation exposure during coronary diagnostic and interventional procedures. In addition, in the recent years, these coronary procedures have been increasingly performed using the radial access for several reasons. However, contradictory results are reported on the radiation exposure of patients from procedures performed by the radial route.[2–7] In the present study, we studied the radiation exposure data of a large real-world patient population undergoing routine coronary angiography (CAG) or PCI. The aims of the study are 2-fold. First, to assess the clinical, angiographic, and procedural characteristics that are associated with increased radiation exposure. Second, to assess whether the radial access route, compared with femoral access route, is associated with increased radiation exposure during CAG and PCI.

Methods

Setting

Our study included CAG and PCI procedures in 5 PCI centers in the Western part of Sweden, Västra Götaland, between January 1, 2008,

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WHAT IS KNOWN

- There are risks of radiation exposure from fluoroscopy-guided procedures.
- The radial access route has become more popular for cardiac angiography.
- Contradictory results reported on increased radiation exposure when performed by the radial route.

WHAT THE STUDY ADDS

- Identifies the clinical and angiographic factors related to increased radiation exposure.
- Demonstrates that radial access route is not necessarily associated with increased radiation exposure.

and January 19, 2012. The 5 PCI centers included in this analysis were (1) Sahlgrenska University Hospital, Gothenburg; (2) Östra Hospital, Gothenburg; (3) Norra Älvborgs Hospital, Trollhättan; (4) Södra Älvsborg Hospital, Borås; and (5) Skaraborg Hospital Skövde, Skövde.

The data about the patient's characteristics and procedural details for the 5 PCI centers were obtained from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). Briefly, this registry holds data on consecutive patients from all 30 centers that perform CAG and PCI in Sweden. The registry is sponsored by the Swedish Health Authorities and is independent of commercial funding. The registry was approved by an institutional review committee in Gothenburg. All consecutive patients undergoing CAG or PCI are included. A diagnostic CAG procedure is described by ≈50 variables, whereas a PCI procedure is described with ≈200 variables. The information about clinical and procedural characteristics is entered into the registry immediately after the procedure by the PCI physician after the review of clinical information. Since 2001, the registry has a Web-based case report platform with automatic data surveillance.[8] At each hospital, a dedicated person is appointed to verify whether all the procedures performed are entered into the registry. Patient variables included clinical (ie, age, risk factors, sex, and cardiac history), angiographic, and procedural characteristics (ie, number of stent implantation and type of lesion).

More than 4500 PCIs and CAGs are performed at the 5 PCI centers each year, from 4574 in 2004 to 6153 procedures in 2011. The centers are teaching institutions, and procedures are routinely performed by a staff interventional cardiologist alone or together with an interventional fellow-in-training. There were 23 interventional cardiologists working within the units during the entire observation period, with experience in both the radial and femoral approaches. For this analysis, we only included procedures performed by a licensed interventional cardiologist, performing ≥100 CAGs via the radial route during the study period.

Data Assembly

Patients on whom PCI was performed have been classified as such. This rule also applied to patients who went for CAG with the option of PCI in the same procedure. All procedural decisions, including device selection and adjunctive pharmacotherapy, were made at the discretion of the operator. A bifurcated lesion was defined as ≥50% narrowing of the vessel diameter involving both the main and side branches, based on visual assessment on the angiogram as assessed by the operator. Chronic total occlusion (CTO) was defined as 100% luminal diameter stenosis and the absence of antegrade flow known or assumed to be ≥12 weeks of duration. In this analysis, access routes were classified according to the first access site, so if first access site was radial but conversion to the femoral route occurred, it was classified as radial based on an intention-to-treat principle. Procedures in which first access site was simultaneously femoral and radial were classified as such in both analyses.

Radiation Measurements and Radiation Protection

The radiation exposure of patients undergoing CAG and PCI was measured using dose–area product (DAP) meters. The DAP is the product of the dose value of the incident radiation and the irradiated field size and is expressed in Gy·cm^2. The DAP meters were integrated in the x-ray systems. The x-ray systems provided direct feedback of the radiation exposure on the monitor of the x-ray systems. The radiation exposure from fluoroscopy mode and cine mode, as well as the total radiation exposure (fluoroscope mode and cine mode), was displayed on the monitor of the x-ray systems. Moreover, the fluoroscopy time (in minutes) was displayed on the monitor. The DAP values and the fluoroscopy time were entered into the SCAAR registry.

The procedures were performed in 5 different hospitals, which included 6 catheterization laboratories in total. Four catheterization rooms are equipped with Philips X-ray systems (Philips Medical Systems, Best, The Netherlands), 3 Integris H5000 systems, and an Allura system.

Two catheterization rooms were equipped with Siemens X-ray systems (Siemens, Erlangen, Germany) an Coroscope, and an Axiom Artis. Field of views were of 25, 19, and 15 cm diagonal square. In the cine mode, the number of frames was variable: either 12.5 or 25 frames/s. The interventional cardiologists used lead aprons and thyroid collars of 0.50-mm lead equivalent thickness at 100 kVp. Furthermore, the interventional cardiologists used ceiling-mounted lead glass screens (Pb equivalent, 0.50 mm) and table shield systems (Pb equivalent, 0.50 mm).

Statistical Analyses

Continuous variables were expressed as mean and SD, and categorical variables were expressed as count and percentage. We made a prediction model for the natural logarithm of the radiation exposure because the distributions of the DAP values were positively skewed. Predictors of radiation exposure were investigated using multivariable linear regression. The primary observational unit was a procedure. Baseline variables that were significant at $P \leq 0.10$ on univariable analysis or variables that were known to be associated with

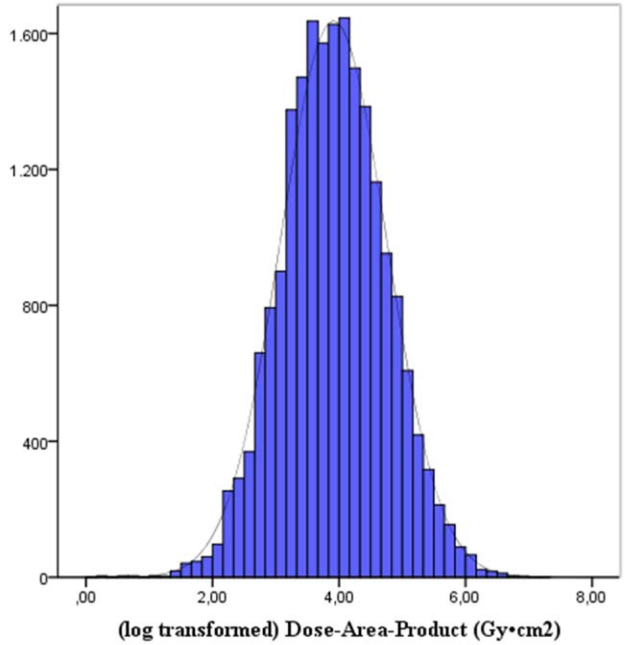

Figure. Distribution of log-transformed dose–area product in the entire study population.

Table 1. Patient and Procedural Characteristics of the Study Population

Baseline Characteristics	N=20 669
Age, y	65.9±11.6
Male sex	68% (14 056)
Body mass index, kg/m²	27.3±5.1
Diabetes mellitus	18% (3719)
Current cigarette smoking	15% (3137)
Hypertension	52% (10 835)
Dyslipidemia	53% (10 879)
History of PCI	23% (4792)
History of CABG	11% (2268)
Date of CAG or PCI	
January 2008–December 2008	27% (5471)
January 2009–December 2009	24% (4869)
January 2010–December 2010	24% (4955)
January 2011–January 2012	26 % (5374)
Indication for CAG	
STEMI	16% (3194)
Unstable angina/NSTEMI	37% (7727)
Stable CAD or other	47% (9748)
Access site	
Femoral	38% (7822)
Radial	59% (12 153)
Both femoral and radial	0.7% (151)
Radial converted to femoral	2% (495)
Femoral converted to radial	0.1% (22)
Axillary or brachial	0.1% (23)
Vessel disease	
0	30% (6138)
1	28% (5779)
2	19% (3817)
3	16% (3339)
LM	7% (1528)
No. of lesions treated per PCI	
0	52% (10 819)
1	27% (5567)
2	13% (2748)
3	5% (1011)
≥4	3% (524)
Treated lesion treated per PCI	
LM	2% (418)
LAD	23% (4753)
LCx	12% (2427)
RCA	16% (3398)
Lesion type	
A	8% (1640)
B1	20% (4135)
B2	17% (3597)
C	11% (2226)
Bifurcation lesion	
1	2% (443)
≥2	1% (221)
Chronic total occlusion	2% (439)
Thrombus aspiration	5% (952)
Cardiogenic shock	1% (225)
Use of aorta balloon pump or other assist devices	2% (307)

CABG indicates coronary artery bypass graft surgery; CAD, coronary artery disease; CAG, coronary angiogram; LAD, left anterior descending artery; LCx, left circumflex artery; LM, left main artery; NSTEMI, non–ST-segment–elevation myocardial infarction; PCI, percutaneous coronary interventions; RCA, right coronary artery; and STEMI, ST-segment–elevation myocardial infarction.

radiation exposure were forced into the model. The database was scrutinized for missing data. Logistic regression showed that several variables predicted a ($P<0.05$) probability of having missing data, including dyslipidemia (3.0% missing), diabetes mellitus (0.8% missing), history of coronary artery bypass graft surgery (CABG; 0.3% missing), and body mass index (BMI; 10.7% missing). Stata (version 12.1) module for multiple imputation was used to estimate missing data and regression modeling. In addition to the complete case analysis, we applied multiple imputation methods to estimate missing data. The imputation protocol consisted of the chain equation method[9] using the same covariates as in the main model with 20 imputed data sets. The imputation procedure and subsequent multivariable regression models were performed according to the Rubin's protocol under the assumption that missing data are missing at random. In the second analysis, we compared the geometric radiation exposure between femoral access and radial access procedures. We adjusted for differences in clinical and procedural characteristics by means of multivariable regression model. Because of the hierarchical structure of our database with the individuals clustered within PCI operators and the operators clustered within hospitals, we have also analyzed the data using multilevel multivariable linear regression to adjust for clustering effect (primary analysis). This is because of the fact that the observations (procedures) performed on the same patient, procedures performed by the same operator, and procedures performed at the same catheterization laboratory are not independent of each other. This causes violation of the assumption of independency. Multilevel modeling adjusts for the correlation between clustered observations by introducing random-effect in the model.[10] Baseline variables that were significant at $P\leq0.10$ on univariable analysis or variables that were known to be associated with radiation exposure were entered into the model. Then, radial access site was forced into the model. In this analysis, patients were excluded in case of preference for the femoral approach, including (1) patients who had a history of CABG, (2) patients with CTO, and (3) patients who were presented with cardiogenic shock or procedures in which intraortic balloon pump or other assist devices were used. All analyses were performed with SPSS (version 19.0; Chicago, IL) and Stata (version 12.1 StataCorp, College Station, TX) software. Statistical significance was considered at $P<0.05$.

Results

Patients

The total number of procedures included in the present study is 20 669, consisting of 10 819 CAGs and 9850 PCIs. In total, 25 291 CAG and PCI procedures were performed during the study period. We excluded procedures not performed by a licensed interventional cardiologist performing ≥100 CAG via the radial route in the study period (n=4057).

Table 2. Multivariable Analysis of Predictors of Radiation Exposure (LnDAP) in the Entire Study Population (Complete Case Analysis)

Multivariable Predictors (N=20 669)	β	Confidence Interval	*P* Value
Intercept	5.69	5.26–6.17	<0.001
Age, per 11.6 y	1.07	1.06–1.08	<0.001
Male sex	1.45	1.42–1.48	<0.001
Body mass index, per 5.1 kg/m^2	1.25	1.24–1.26	<0.001
Diabetes mellitus	1.06	1.03–1.08	<0.001
Dyslipidemia	1.02	1.01–1.04	0.013
History of CABG	1.32	1.28–1.35	<0.001
Date of CAG or PCI			
January 2009–December 2009	0.92	0.34–0.94	<0.001
January 2010–December 2010	0.87	0.84–0.89	<0.001
January 2011–January 2012	0.78	0.76–0.80	<0.001
Access site			
Radial	1.01	0.99–1.03	0.17
Femoral	0.97	0.90–1.05	0.36
Axillary or brachial	1.34	1.03–1.72	0.03
Vessel disease			
0	0.83	0.80–0.85	<0.001
1	1.15	1.13–1.19	<0.001
2	1.26	1.22–1.30	<0.001
3	1.30	1.26–1.34	<0.001
No. of lesions treated per PCI			
0	0.93	0.87–0.99	<0.001
1	1.62	1.57–1.68	<0.001
2	1.95	1.84–2.03	<0.001
3	2.34	2.16–2.53	<0.001
≥4*	2.83	2.53–3.16	<0.001
Treated lesion			
LM	1.09	1.12–1.19	0.03
LAD	1.06	1.01–1.11	<0.001
LCx	1.01	0.71–1.31	0.59
RCA	1.04	1.01–1.07	0.003
Lesion type			
A	0.94	0.90–0.98	0.008
B1	1.03	1.00–1.06	<0.001
B2	1.05	1.02–1.08	<0.001
C	1.11	1.07–1.14	<0.001
CTO lesion	1.39	1.31–1.48	<0.001
Bifurcation lesion	1.14	1.06–1.21	<0.001
Thrombus aspiration	1.11	1.06–1.16	<0.001
Hospital			
1	1.02	0.95–1.09	0.27
2	0.65	0.62–0.69	<0.001
3	1.01	0.71–1.31	0.59
4	0.81	0.76–0.86	<0.001
5	0.73	0.46–1.15	0.18
Operators (1–23)	0.64–1.62	0.63–1.67	<0.001

β indicates estimated regression coefficient; CABG, coronary artery bypass graft surgery; CAG, coronary angiogram; CTO, chronic total occlusion; LAD, left anterior descending artery; LCx, left circumflex artery; LM, left main artery; PCI, percutaneous coronary interventions; and RCA, right coronary artery.

*Confidence interval not symmetrical because of rounding issues.

Table 3. Multiple Analyses of Predictors of Radiation Exposure (LnDAP) to Assess Whether Radial Access Site (Compared With Other Access Site) Is Associated With Increased Radiation Exposure

	β	Confidence Interval	*P* Value
Complete case multivariable linear regression	1.00	0.98–1.03	0.67
Imputed multivariable linear regression*	1.01	0.99–1.05	0.27
Complete case multilevel linear regression	1.00	0.98–1.03	0.49
Imputed multilevel linear regression*	1.01	0.99–1.05	0.24

β indicates estimated regression coefficient.
*Confidence interval not symmetrical because of rounding issues.

Mean log-transformed DAP in our study population was 3.91±0.84 (Figure). Radiation exposure data were not available for 565 patients. Clinical and angiographic characteristics of patients with missing radiation exposure data were similar to the study population (data not shown). In Table 1, patient and procedure characteristics of the entire study population are shown. The study population consisted of 68% men, 18% patients with diabetes mellitus, and 11% patients with a history of CABG. In 59% of the procedures, access route was radial, and 4.0% of all radial procedures were converted to the femoral access site (n=495).

The results of the multilevel regression analysis for radiation exposure are shown in Table 2. Multivariable predictors of increased radiation exposure were age, male sex, high BMI, diabetes mellitus, dyslipidemia, history of CABG, number of diseased vessels, number of lesions treated, and complex lesion type (type B1, B2, C, bifurcation lesions, and CTO). Also, thrombus aspiration and the use of intraortic balloon pump or other assist devices were associated with increased radiation exposure. Moreover, there was a wide range of radiation exposure associated with each interventional cardiologist. Among these predictors, BMI (per 5.1 g/m^2; β=1.25; confidence interval [CI], 1.24–1.26; *P*<0.001); history of CABG (β=1.32; CI, 1.28–1.32; *P*<0.001); 2, 3, or 4 treated lesions (2 treated lesions: β=1.95; CI, 1.84–2.03; *P*<0.001; 3 treated lesions; β=2.34; CI, 2.16–2.53; *P*<0.001; and 4 treated lesions: β=2.83; CI, 2.53–3.16; *P*<0.001); and chronic total lesions (β=1.39; CI, 1.31–1.48; *P*<0.001) were associated with the highest radiation exposure. During the study period, radiation exposure decreased with time. After imputation of missing values, the multivariable predictors of radiation exposure did not differ.

In a second analysis, we assessed whether the radial access route is associated with increased radiation exposure. In this analysis, patients with a history of CABG (n=2268), a CTO (n=439), or >2 bifurcated lesions (n=221) and patients who were presented with cardiogenic shock (n=225) or procedures in which intraortic balloon pump or other assist devices were used (n=307) were excluded from the analysis. Two hundred fifty-six procedures had ≥2 of these characteristics, 32 procedures had 3 characteristics, and 2 procedures had 4 exclusion criteria, making a total of 17 535 procedures. Of these 17 535 procedures, 17 procedures were treated using the axillary or brachial access route, 103 with simultaneously femoral and radial access site, and access site of 3 procedures was missing. These procedures were excluded, making a total of 17 412 procedures included in the second analysis.

Median DAP value was 48 (interquartile range [IQR], 28–85) Gy·cm^2 for procedures performed via femoral route (n=5742) compared with 44 (26–75) Gy·cm^2 for procedures performed via radial route (n=11 670; *P*<0.001). Median radiation exposures of the patients undergoing a PCI via the femoral route (n=2792) was 79 (51–122) Gy·cm^2 compared with 73 (48–112) Gy·cm^2 for procedures performed via radial route (n=5056; *P*<0.001). The median exposure for CAGs was 31 (21–47) Gy·cm^2 and 31 (20–46) Gy·cm^2 for procedures performed via femoral route (n=2950) and procedures performed via radial route (n=6614; *P*=0.18), respectively. After multivariable analysis, radial access route remained not associated with increased radiation exposure (β=0.004; SE=0.001; *P*=0.67). Also after imputing missing values, in multilevel analysis, radial access route did not lead to increased radiation exposure (Table 3).

Discussion

In the largest study population to assess radiation exposure in CAG and PCI, we found that high BMI, history of CABG, number of treated lesions, and CTOs were associated with the highest patient radiation exposure. Radial access site was not associated with higher radiation exposure.

A previous study of 1287 male and 540 female patients undergoing PCI also found that lesion complexity, PCI of left circumflex artery, and number of lesions treated were correlated with increased radiation exposure.[11] Other factors that were associated with increased radiation exposure were body mass index, previous CABG, and peripheral vascular disease. However, in that study, exposure in air values (R, type 1) and the air kerma values (Gy, type 2) were measured and were converted to cumulative skin dose. However, estimations of effective doses[12] of patients using DAP measurements may be more accurate than using air kerma measurements because DAP allows for variations in field size.[13]

In this study, we found that high BMI, history of CABG, CTO lesions, and 2, 3, or 4 treated lesions were associated with the highest radiation exposure. Although these factors cannot be directly influenced before conducting the CAG or PCI, it is important to know these factors so that patients can be adequately informed. Also, when treating complex or CTO lesions, especially in patients with high BMI or previous CABG, radiation management can be incorporated into preprocedure planning as well as in defining maximum levels that could guide physicians in decision making during the procedure accordingly. Finally, we and Fetterly et al[11] have demonstrated that individual PCI operators have a substantial influence on patient dose. Therefore, all staff and trainee physicians should be well trained in behavioral and technical methods to minimize radiation dose.

Several reports have compared the radiation exposure of patients from procedures performed by the radial route with procedures performed by the femoral route with contradictory results. Sandborg et al[2] reported higher exposure of patients from procedures performed by the radial route for both PCIs and CAGs. In their study, the interventional cardiologists were experienced in performing the procedures by the femoral route, whereas the radial route was used as a complementary technique to the femoral route. Lange and von Boetticher[3] also reported higher exposure of patients for CAG procedures assessed by the radial route, whereas for PCI procedures, the exposure did not differ between both access routes. The higher exposure for CAGs performed by the radial route was explained by a higher fluoroscopy time because of difficulties in advancing the catheter across the aortic arch. Finally, 2 other studies also reported higher exposure of patients from procedures performed by the radial route.[4,5] However, in 1 study, the mean body weight of the group of patients treated by the femoral route was lower compared with the mean body weight of the group of patients who underwent the procedures by the radial route.[4] In the other study, the air kerma (in Gy) was used as a measure for radiation exposure[5] The findings from the present study were comparable with the findings reported by Geijer and Persliden[6] and Kuipers et al.[7] In these studies, radial access site was not associated with increased radiation exposure.

The RadIal Vs femorAL access for coronary intervention (RIVAL) study was a large, randomized trial comparing radial and femoral access for CAG and intervention.[14] Duration of fluoroscopy was higher in the radial access group (9.3 [5.8–15] minutes) compared with that in the femoral access group (8.0 [4.5–13] minutes). However, the authors did not directly measure radiation exposure. Moreover, the average annual operator's volume was relatively low.

Our analysis has several limitations. The radiation dose received by a patient during an interventional procedure is highly variable and is also dependent on many technical factors. This is partly reflected by a substantial variability in radiation exposure observed among the interventional cardiologists in our study population. The technical factors affecting radiation dose are x-ray imaging type and fluoroscopic and acquisition imaging dose rate settings. Unfortunately, in this analysis, we did not take these factors into account. It is likely that the mode of operation contributed to the variation in exposure of the patients. It is also possible that differences in distance to the patients during exposures contributed to the variation in patients' exposure, for instance, the position of the x-ray tube, the height of the table, and the distance between patient and image intensifier during the procedures. We did not measure these variables and were, therefore, unable to include them in the statistical models. However, we did apply multilevel modeling, which is a recommended statistical approach in the case of clustering of observations.[3] Moreover, the radiation exposure of the interventional cardiologists was not measured. During interventional procedures performed by the radial route, the interventional cardiologists are usually closer to patients than during procedures performed by the femoral route. Because the intensity of scattered radiation close to patients is higher than the intensity at greater distances, it is possible that the radiation exposure of interventional cardiologists from procedures performed by the radial route is higher compared with exposure from procedures performed by the femoral route. However, in a previous study,[15] a linear relation was found between the exposure of 4 weekly measurements measured outside the lead aprons of the interventional cardiologists and the exposure of patients, irrespective of the interventional cardiologists or number of performed radial/femoral procedures. In conclusion, we found that high BMI, history of CABG, number of treated lesions, and CTOs were associated with the highest patient radiation exposure. Radial access site was not associated with higher radiation exposure when compared with femoral approach.

Disclosures

None.

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