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Radiation Exposure During Percutaneous Coronary Interventions and Coronary Angiograms Performed by the Radial Compared With the Femoral Route

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Objectives This study aimed to compare radiation exposure of patients undergoing percutaneous coronary interventions (PCI) and coronary angiograms (CAG) accessed by the femoral route with the radial route (operator's choice).

Background There are limited and contradictory data on the radiation exposure of patients during PCI and CAG performed by the radial route compared with the femoral route.

Methods Data on the radiation exposure of patients from 3,973 PCI and CAG procedures between June 22, 2004, and December 31, 2008, were prospectively collected and analyzed. A prediction model was made for radiation exposure (dose-area product in Gy·cm^2) based upon the femoral access group, and the group of radial performed procedures was compared to assess differences between observed and expected radiation exposure.

Results Median exposures of patients undergoing a PCI via the femoral route (n = 2,309) was 75 (interquartile range [IQR]: 44 to 135) Gy·cm^2 compared with 72 (IQR: 42 to 134) Gy·cm^2 for radial performed procedures (n = 1,212) (p = 0.30). Median exposure for CAGs was 44 (IQR: 31 to 69) Gy·cm^2 and 40 (IQR: 25 to 65) Gy·cm^2 for, respectively, femoral (n = 314) and radial performed procedures (n = 138), (p = 0.31). Also, the observed radiation exposure in patients undergoing radial PCI or CAGs was not higher than the expected exposure of patients as predicted by the femoral access-based prediction model (71.5 ± 2.3 Gy·cm^2 vs. 79.9 ± 1.8 Gy·cm^{2,}).

Conclusions The study shows that even after correction for the complexity of the procedures, selected procedures performed by the radial route are not associated with higher radiation exposure of patients than selected procedures performed by the femoral route. (J Am Coll Cardiol Intv 2012; 5:752–7) © 2012 by the American College of Cardiology Foundation

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The femoral route has traditionally been the preferred access site for percutaneous coronary interventions (PCIs) and coronary angiograms (CAGs). In 1989, the radial route was first introduced, and since then, the number of procedures performed by the radial route increased as the technique evolved with improvement in catheter design and with interventional cardiologists' experience (1). Advantages of the radial access route include less bleeding and fewer vascular complications, whereas the success rate is similar compared with procedures performed by the femoral route (2).

The radiation exposure during fluoroscopy-guided procedures became a topic of concern as the number of procedures increased during the years. In Publication 85 of the International Commission on Radiological Protection (ICRP) (3), the risks of radiation exposure from fluoroscopy-guided procedures are described. The ICRP reported an increase of radiation-induced injuries to patient's skin (deterministic effect) as well as the risk to develop radiation-induced cancers (stochastic effect).

Over the years, contradictory results were reported on the radiation exposure of patients from procedures performed by the radial route (4–8). In the present study, we report radiation exposure data of a large, real-world patient population undergoing routine PCI or CAG. The aim of the study was to compare radiation exposure of patients during PCI and CAG accessed by either the radial or the femoral route.

Methods

Setting. This study used data that were prospectively collected between 2004 and 2008 as part of a local cardiac catheterization registry at a high-volume tertiary cardiac care center in Amsterdam, the Netherlands. Over 2,000 PCIs and 1,200 CAGs are performed at this center each year. The center is a teaching institution, and procedures are routinely performed by a staff interventional cardiologist alone, or together with an interventional fellow-in-training. There were 6 interventional cardiologists working within the unit during the entire observation period, with experience in both the radial and femoral approaches. In the study period, all operators performed at least 800 procedures using a femoral access site and 200 procedures using a radial access site. Radial approach was right sided. At PCI or CAG, the patient-specific data were entered into an electronic database by qualified catheterization laboratory personnel and interventional cardiologists. Patient variables included clinical (i.e., age, risk factors, sex, and cardiac history), angiographic, and procedural characteristics (i.e., number of stents implanted, type of lesion).

Patient population. Our present study included all patients in the Academic Medical Center who had undergone PCI or CAG between June 22, 2004, and December 31, 2008. In general, patients treated using the femoral approach were excluded: 1) patients were referred for an emergency PCI (e.g., rescue or primary for ST-segment elevation myocardial infarction) or procedures for noncoronary interventions; 2) patients had a history of coronary artery bypass graft (CABG); and 3) patients had a chronic total occlusion or more than 2 bifurcated lesions. A bifurcated lesion was defined as ≥50% narrowing of the vessel diameter involving both the main and side branch, based on visual assessment on the angiogram as assessed by the operator. PCIs and CAGs were performed using standard techniques. Patients in whom PCI was performed have been classified as such. This rule also applied to patients who went for CAG with the option of PCI.

All patients were treated with heparin and aspirin before PCI. All procedural decisions, including device selection and adjunctive pharmacotherapy, were made at the discretion of the operator. For this analysis, we only included procedures performed by a licensed interventional cardiologist.

Dose-area product values and catheterization laboratory equipment. The radiation exposure of patients undergoing PCI and CAG 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 (Diamentor, PTW-Freiburg, Germany/KermaX-plus, Wellhöfer, Germany) were integrated in the X-ray systems. The X-ray systems provided direct feedback of the radiation exposure on the monitor of the systems. The radiation exposure from fluoroscopy mode and cine mode as well as the total radiation exposure (fluoroscopic 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 meters were calibrated at regular intervals with a reference dosimeter (Unforce Xi, Bildall, Sweden). The DAP values as well as the fluoroscopy time were entered into a dedicated electronic database that was linked to the catheterization registry database.

Abbreviations and Acronyms

CABG = coronary artery bypass graft
CAG = coronary angiogram
DAP = dose-area product
ICRP = International Commission on Radiological Protection
IQR = interquartile range
PCI = percutaneous coronary intervention

The procedures were carried out in 3 different catheterization rooms. The catheterization rooms were equipped with Philips X-ray systems (Philips Medical Systems, Best, the Netherlands). Two Integris H5000 systems, and an Allura 9C flat panel system were used with field of views of 25-, 19-, and 15-cm diagonal square. The entrance exposure rate in the fluoroscopy mode of the X-ray systems varied between 40 mGy·min^{-1} in the low-dose mode up to 80 and 160 mGy·min^{-1} in the normal- and high-dose modes. The

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inherent filtration of the X-ray systems was 2.4 mm Al equivalent. In the low- and normal-dose modes, additional filters of 0.4 mm Cu and 0.1 mm Cu, respectively, were automatically added. In the high fluoroscopy mode and in the cine mode, no additional filters were inserted. All X-ray systems used 25 pulse·s^{-1} in the normal- and high-dose modes. In the low-dose mode, the pulse rate for the Allura 9C was 12.5 pulse·s^{-1}, whereas for the Integris H5000, the pulse rate was continuously adjusted. In the cine mode, the number of frames was variable: either 12.5 frames·s^{-1} or 25 frames·s^{-1}.

The interventional cardiologists used lead aprons and thyroid collars of 0.50-mm lead equivalent thickness at 100 kVp (Medical Development and Technology BV, Hilvarenbeek, the Netherlands). Furthermore, the interventional cardiologists used ceiling-mounted lead glass screens (Pb equivalent: 0.50 mm, MAVIG, Munich, Germany) and table shield systems (Pb equivalent: 0.50 mm, Kenex (Electro-Medical), Harlow, United Kingdom).

Statistical analyses. We compared DAP values of procedures accessed by the femoral route with those of the radial route by Mann-Whitney *U* test. To reduce the effect of selection bias and potential confounding of all clinical and procedural characteristics in this observational study, we made a prediction model for the natural logarithm (Ln) of the radiation exposure based upon the femoral access group because the distribution of the DAP values were positively skewed. We then compared the geometric mean to the group of radial performed procedures to assess differences between observed and expected radiation exposure. Clinical and procedural characteristics were described by category of access route. Continuous variables were expressed as mean and standard deviation. Differences between groups were assessed by unpaired Student *t* test or Mann-Whitney *U* test as appropriate. Categorical variables were expressed as count and percentage, and were tested with the chi-square test or Fisher exact test, as appropriate. Covariates of interest as predictors of radiation were investigated using multivariable linear regression. Baseline variables that were significant at $p \leq 0.10$ on univariate analysis were entered into a multivariate model. The prediction model was used to correct for differences in patient and procedural characteristics treated by the radial and femoral routes. Statistics were performed with SPSS version 18.0.1 (Chicago, Illinois). Statistical significance was considered as p value <0.05.

Results

Patients. The total number of procedures included in the present study is 2,623 for procedures performed by the femoral route and 1,350 for procedures performed by the radial route. In total, 10,905 PCI and CAG procedures were performed during the study period. Excluded procedures were procedures performed by a fellow in training (n = 1,217), emergency PCIs (n = 2,985), patients with a history of CABG (n = 670), chronic total occlusion (n = 424), and patients with more than 2 bifurcated lesions (n = 760). Radiation exposure data were not available for 876 patients. Clinical and angiographic of patients with missing radiation exposure data were comparable to the study population (data not shown). In Table 1, patient and procedure characteristics are shown, stratified by access route.

Median DAP value was 69 (interquartile range [IQR]: 40 to 126) Gy·cm^2 for femoral performed procedures compared with 69 (IQR: 40 to 128) Gy·cm^2 for procedures performed via the radial route (p = 0.76). Median fluoroscopy time was 12.4 (IQR: 7.4 to 20.6) min versus 11.0 (IQR: 6.9 to 18.2) min for, respectively, the femoral and radial access routes ($p < 0.001$). Median radiation exposures of the patients undergoing a PCI via the femoral route (n = 2,309) was 75 (IQR: 44 to 135) Gy·cm^2 compared with 72 (IQR: 42 to 134) Gy·cm^2 for radial performed procedures (n = 1,212) (p = 0.30). The median exposure for CAGs was 44 (IQR: 31 to 69) Gy·cm^2 and 40 (IQR: 25 to 65) Gy·cm^2 for, respectively, femoral (n = 314) and radial performed procedures (n = 138) (p = 0.31).

The results of the multiple regression analysis from procedures performed by the femoral route are shown in Table 2. Multivariate predictors of radiation exposure were male sex, body mass index, number of lesions, type C lesions, right coronary artery lesions, left circumflex coronary lesions, and type of imaging system. Moreover, each interventional cardiologist was considered as a predictor for the radiation exposure.

In Table 3, the results of the expected radiation exposures based upon the prediction model derived in the femoral access group was compared with the observed radiation exposures of procedures accessed via the radial route. The observed radiation exposure in patients undergoing radial PCIs or CAGs was not higher than the expected exposure of patients as predicted by the femoral access–based prediction model (71.5 ± 2.3 Gy·cm^2 vs. 79.8 ±1.8 Gy·cm^2 [geometric mean]).

Table 3 also shows decreased radiation exposure with increased operator experience (88.2 ± 2.4 Gy·cm^2 in 2004 to 2005 vs. 66.2 ± 2.3 Gy·cm^2 in 2007 to 2008, [geometric mean]).

Discussion

In our study, the exposure of patients did not differ between procedures performed by the radial route or the femoral route. The median exposure was 69 Gy·cm^2 both in procedures performed by the radial route and by the femoral route (PCI and CAG). Even after correction for complexity of the procedures, selected procedures via the radial route are not associated with higher radiation exposure for patients than selected procedures via the femoral route.

Table 1. Patient and Procedural Characteristics by Category of Access Route

Baseline Characteristic	Femoral Route (n = 2,623)	Radial Route (n = 1,350)	p Value
Age, yrs	63 ± 9	64 ± 11	0.03
Male	69%	74%	0.001
Body mass index, kg/m^2	27 ± 4	27 ± 4	0.66
Diabetes mellitus	20%	21%	0.93
Known hypertension	47%	50%	0.12
Family history of coronary heart disease	54%	47%	0.47
Hypercholesterolemia	42%	40%	0.15
Current cigarette smoking	24%	23%	0.38
History of PCI	35%	39%	0.35
Use of vitamin K antagonist	3%	5%	0.001
Multivessel disease	31%	28%	0.04
Date of CAG or PCI			
July 2004 to December 2005	40%	10%	<0.001
January 2006 to June 2007	37%	36%	0.49
July 2007 to December 2008	23%	54%	<0.001
Operator			
1	17%	11%	<0.001
2	17%	17%	0.77
3	20%	36%	<0.001
4	22%	13%	<0.001
5	14%	14%	0.96
6	10%	10%	0.55
CAG	12%	10%	0.10
PCI			
Lesions treated per PCI, n			
1	68%	68%	0.65
2	25%	25%	1.00
3	6%	6%	0.65
Location of lesion			
LAD	51%	52%	0.44
LCX	33%	33%	0.58
RCA	35%	36%	0.37
Lesion type			
A	8%	8%	0.28
B1	28%	28%	0.84
B2	33%	37%	0.045
C	26%	19%	<0.001
Lesion calcification	30%	27%	<0.01
Proximal coronary vessel tortuosity	8%	8%	0.79
Post-dilation	49%	49%	0.83
Thrombus aspiration	2%	2%	0.25
Bifurcation lesion	11%	10%	0.06
Fluoroscopy time, min	12.4 (7.4–20.6)	11.0 (6.9–18.2)	<0.001
Allura imaging system	52%	60%	<0.001

Values are mean ± SD, %, or median (25th to 75th percentile).
CAG = coronary angiogram; LAD = left anterior descending artery; LCX = left circumflex artery; PCI = percutaneous coronary intervention; RCA = right coronary artery.

Table 2. Multivariate Analysis of Predictors of Radiation Exposure (LnDAP) Performed by the Femoral Route

Predictor	B	SE	Exp B	p Value
Intercept	2.78	0.097	16.11	0.001
Male	0.26	0.028	1.30	<0.001
Body mass index, kg/m^2	0.05	0.003	1.05	<0.001
No. of lesions treated	0.24	0.022	1.27	<0.001
Type C lesion	0.48	0.031	1.62	<0.001
Location of lesion				
RCA	0.17	0.025	1.18	<0.001
LCX	0.12	0.027	1.12	<0.001
Operator 1*	−0.62	0.044	−1.86	<0.001
Operator 2*	−0.79	0.043	−2.20	<0.001
Operator 4*	−0.36	0.04	−1.44	<0.001
Operator 5*	−0.33	0.047	−1.39	<0.001
Operator 6*	−0.06	0.04	−1.06	0.007
Allura imaging system†	0.24	0.027	1.27	<0.001

*Relative to Operator 3 (reference); Operator 3 was the most experienced operator, with the highest volume. Operator 3 was also the operator with the highest radiation exposure. †Relative to Integris imaging system.
LnDAP = natural logarithm of the dose-area product; other abbreviations as in Table 1.

In Table 4, radiation exposure levels of patients reported by previous studies are shown (4–8). Sandborg et al. (8) reported higher exposure of patients from procedures performed by the radial route than procedures performed by the femoral 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 et al. (5) 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 due to difficulties in advancing the catheter across the aortic arch. Brasselet et al. (6) reported the exposure of patients for CAGs and PCIs. They found higher exposure of patients from procedures performed by the radial route. However, the results reported in their study

Table 3. Geometric Mean of Observed and Expected DAP (in Gy·cm^2) of Procedures Performed by the Radial Route

		Geometric Mean of DAP		
	n	Observed (Gy·cm^2)	Expected (Gy·cm^2)	Observed-Expected (Gy·cm^2)
Overall	1,350	71.5 ± 2.3	79.8 ± 1.8	−8.3 ± 1.9
Date of PCI				
July 2004 to December 2005	135	88.2 ± 2.4	110.0 ± 1.8	−21.8 ± 2.0
January 2006 to June 2007	482	74.4 ± 2.3	80.6 ± 1.8	−6.2 ± 1.8
July 2007 to December 2008	733	66.6 ± 2.3	75.2 ± 1.8	−8.6 ± 1.8
Age <65 yrs	625	72.9 ± 2.3	83.1 ± 1.8	−10.2 ± 1.8
Body mass index <29 kg/m^2	382	91.8 ± 2.2	105.5 ± 1.7	−13.7 ± 1.8
Lesion type C	255	134.3 ± 2.1	148.4 ± 1.6	−14.1 ± 1.9

DAP = dose-area product; PCI = percutaneous coronary intervention.

Table 4. Radiation Exposure of Patients Stratified by PCIs and CAGs Reported in Earlier Studies

Study/First Author (Ref. #)	PCI					CAG				
	Femoral Access		Radial Access			Femoral Access		Radial Access		
	n	DAP (Gy·cm^2)	n	DAP (Gy·cm^2)	p Value	n	DAP (Gy·cm^2)	n	DAP (Gy·cm^2)	p Value
Present study	2,309	75	1,212	72	NS	314	44	138	40	NS
Sandborg et al. (4)	42	47	24	75	<0.05	40	38	36	51	<0.05
Lange et al. (5)	48	51	54	46	NS	103	13	92	15	<0.05
Brasselet et al. (6)	83	103	90	126	<0.05	98	38	150	59	<0.05
Geijer et al. (7)	114	70	55	71	NS	—	—	—	—	—

NS = not significant; other abbreviations as in Tables 1 and 3.

were biased because 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 that underwent the procedures by the radial route. The findings in the present study were comparable to the findings reported by Geijer et al. (7). They reported radiation exposure of patients for PCIs. They reported radiation exposure of patients for PCIs and concluded that the exposure of patients does not increase when using the radial access route. Mercuri et al. (8) reported about the air kerma (in Gy) as a measure for radiation exposure of patients. They reported higher exposures of patients from procedures accessed by the radial route compared with the femoral route. However, estimations of effective doses (9) of patients using DAP measurements may be more accurate than using air kerma measurements, as DAP allows for variations in field size (10). The RIVAL (RadIal Vs femorAL access for coronary intervention) study was a large randomized trial comparing radial and femoral access for coronary angiography and intervention (11). Duration of fluoroscopy was higher in the radial access group, 9.3 (5.8 to 15) min compared with 8.0 (4.5 to 13) min in the femoral access group. However, the authors did not directly measure radiation exposure. Moreover, the average annual operator's volume was relatively low compared with our high-volume center. As our data suggest, increased radiation exposure decreases with increasing experience.

In the present study, data on the radiation exposure of patients undergoing routinely performed PCI or CAG were reported. All data included in the study were from procedures performed in a tertiary primary PCI center by interventional cardiologists with extensive experience in performing procedures by the radial and the femoral route.

In the multiple regression analysis, each interventional cardiologist is described as a predictor of the exposure of the patients. It is likely that the mode of operation contributed to the variation in exposure of the patients. Since the interventional cardiologists in the department have different preferences regarding the use of the cine mode and the 3 different fluoroscopy modes, the mode of operation is responsible for the variation in exposure of patients. It is also possible that differences in distance to the patients during exposures, such as the position of the X-ray tube, the height of the table, and the distance between patient and image intensifier during the procedures, contributed to the variation in patients' exposure. We did not measure these variables, and it is uncertain to what extend the variation in the model is caused by these variables. Moreover, the radiation exposure of the interventional cardiologists was not measured in the present study. During interventional procedures performed by the radial route, the interventional cardiologists are usually closer to patients than during procedures performed by the femoral route. Since 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 the exposure from procedures performed by the femoral route. However, in a previous study (12), a linear relation was found between the exposure of monthly 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.

The procedures in the study were performed at a high-volume center by interventional cardiologists with extensive experience in performing procedures by the radial and the femoral routes. Therefore, our results can only be applied to centers where procedures are performed by interventional cardiologists with sufficient experience in both the femoral and the radial routes. Also, we do not have data on conversion from radial access to femoral access sites. It is not known to what extend the results can be applied to other centers where the radial route is used as a complementary technique to the femoral route, and interventional cardiologists are less experienced in performing procedures by the radial route.

Study limitations. This is an observational study in which patients were selected for radial or femoral access, quite likely based on the operators' perception of technical difficulty

and procedural duration associated with one approach versus the other. With technical difficulty being strongly associated with radiation exposure, it can be expected that the selection process greatly influenced the radiation exposure results.

Conclusions

The study shows that even after correction for the complexity of the procedures, selected procedures performed by the radial route are not associated with higher radiation exposure of patients than selected procedures performed by the femoral route.

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