

RADIATION SAFETY

# Effect of Vascular Access Site Choice on Radiation Exposure During Coronary Angiography



## The REVERE Trial (Randomized Evaluation of Vascular Entry Site and Radiation Exposure)

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### ABSTRACT

**OBJECTIVES** This study sought to perform a randomized noninferiority trial of radiation exposure during cardiac catheterization comparing femoral access (FA) with left radial access (LRA) and right radial access (RRA).

**BACKGROUND** Increased radiation exposure with radial approach compared with femoral approach remains a controversial issue.

**METHODS** This study randomized 1,493 patients undergoing cardiac catheterization at a tertiary care center to FA, LRA, and RRA in a 1:1:1 fashion. The primary endpoint was air kerma. The secondary endpoints included dose-area product, fluoroscopy time and operator dose per procedure, number of cineangiograms, and number of catheters.

**RESULTS** Baseline and procedural characteristics were similar among groups. No significant differences were observed in air kerma (medians: FA: 421 mGy [interquartile range (IQR): 337 to 574 mGy], LRA: 454 mGy [IQR: 331 to 643 mGy], and RRA: 483 mGy [IQR: 382 to 592 mGy],  $p = 0.146$ ), dose-area product (medians: FA: 25.5 Gy cm<sup>2</sup> [IQR: 19.6 to 34.5 Gy cm<sup>2</sup>], LRA: 26.6 Gy cm<sup>2</sup> [IQR: 19.5 to 37.5 Gy cm<sup>2</sup>], and RRA: 27.7 Gy cm<sup>2</sup> [IQR: 21.9 to 34.4 Gy cm<sup>2</sup>],  $p = 0.40$ ), or fluoroscopy time (medians: FA: 1.3 min [IQR: 1.0 to 1.7 min], LRA: 1.3 min [IQR: 1.0 to 1.7 min], and RRA: 1.32 min [IQR: 1.0 to 1.7 min],  $p = 0.19$ ) among the 3 access sites. Median operator exposure was higher in the LRA group (3 mrem [IQR: 2 to 5 mrem],  $p = 0.001$  vs. FA, and  $p = 0.0001$  vs. RRA) compared with the FA (2 mrem [IQR: 2 to 4 mrem]) and RRA groups (3 mrem [IQR: 2 to 5 mrem]).

**CONCLUSIONS** Radiation exposure to patients was similar during diagnostic coronary angiography with FA, RRA, and LRA. However, LRA was associated with significantly higher operator radiation exposure than were FA and RRA procedures. (Randomized Evaluation of Vascular Entry Site and Radiation Exposure [REVERE]; [NCT01677481](https://clinicaltrials.gov/ct2/show/study/NCT01677481)) (J Am Coll Cardiol Intv 2015;8:1189-96) © 2015 by the American College of Cardiology Foundation.

**R**adiation burden of coronary angiographic and interventional procedures is a major concern for patients as well as operators. Studies comparing radiation exposure between transradial access (TRA) and transfemoral access (TFA) have reported varying results (1-4). Concerns over

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## ABBREVIATIONS AND ACRONYMS

AK = air kerma

DAP = dose-area product

FA = femoral access

FT = fluoroscopy time

IQR = interquartile range

LRA = left radial access

PCI = percutaneous coronary intervention

RRA = right radial access

TFA = transfemoral access

TRA = transradial access

increased radiation exposure with TRA may discourage some operators from adopting TRA, which has been shown to reduce access site bleeding and major vascular complications, is preferred by patients, and is cost-effective compared with TFA (5-8). Because operator proficiency with TRA has been shown to be associated with radiation exposure (9), whether the results of several observational as well as randomized studies are explained by variation in operator experience with TRA is unknown. In addition, most studies have not distinguished between left and right radial access sites despite the fact that these 2 radial access sites have differential impacts on radiation exposure and procedure time (10).

There is no prospective randomized study comparing femoral access (FA) to left radial access (LRA), and right radial access (RRA) with respect to radiation exposure to patients and operators. Accordingly, we performed a randomized trial comparing these 3 access site approaches involving operators with varying degrees of proficiency with RRA and LRA as well as TFA.

## METHODS

**PATIENT POPULATION.** Adult patients (age >18 years) referred for cardiac catheterization at a tertiary care center in India involving 5 operators were randomized to FA, LRA, or RRA. Inclusion and exclusion criteria are outlined in Table 1. A 1:1:1 randomization schedule was used, using a sequentially numbered opaque sealed envelope method (11). The local ethics committee approved the study. All patients provided written informed consent per hospital protocol.

**ARTERIAL ACCESS. Femoral access.** After sterile preparation and 2% lidocaine infiltration, femoral artery access was obtained using an anterior wall puncture technique with a 16-gauge needle, and a 5-F nonhydrophilic introducer sheath (Pinnacle, Terumo Medical, Tokyo, Japan) was inserted in standard fashion. Diagnostic coronary angiography was performed according to standard practice with the use of devices and pharmacotherapy per the operator's discretion. Hemostasis in all femoral cases was achieved using manual compression.

**Radial access.** Radial artery access was obtained with a 20-gauge Teflon-sheathed needle using the counter puncture technique (12). A 5-F hydrophilic-coated introducer sheath (Radio Focus, Terumo Medical) was inserted in the radial artery. An intra-arterial vasodilator cocktail was administered consisting

TABLE 1 Inclusion and Exclusion Criteria

Inclusion criteria
Patients age >18 yrs
Undergoing diagnostic coronary angiography
Signed informed consent
Exclusion criteria
History of previous coronary artery bypass graft surgery
Abnormal anatomy precluding use of FA, LRA, or RRA access site.
Ad hoc PCI

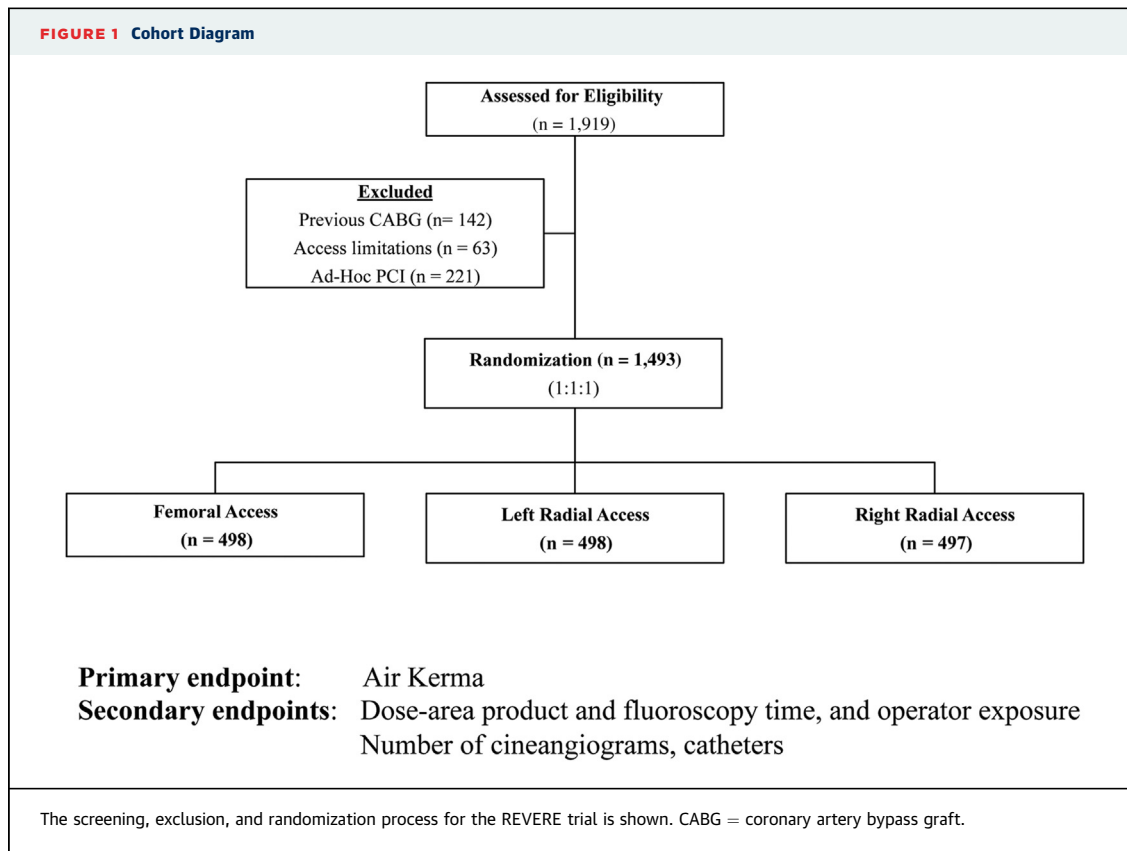
FA = femoral access; LRA = left radial access; PCI = percutaneous coronary intervention; RRA = right radial access.

of nitroglycerin 200 µg and verapamil 5 mg after sheath insertion. Unfractionated heparin (50 U/kg) was administered intravenously after sheath insertion. Specific catheter choices were left to the operator's discretion. The introducer sheath was removed at the end of the procedure, and an inflatable pressure band (TR-band, Terumo Medical) was applied to the access site to achieve hemostasis.

Demographic and medical history data including age, sex, history of diabetes mellitus, hypertension, height, and weight were collected. The number of catheters used to complete the procedure was also recorded. Operators used Judkins catheters, Amplatz left and right coronary catheters (Cordis Corporation, Fremont, California) and universal catheters, including the Tiger catheter and Jackie catheter (Terumo Medical). The number of views for angiography was left to the discretion of the operator. Lead shields placed under the catheterization table, as well as ceiling-mounted lead shields, were used in every procedure. Procedural success was defined as satisfactory acquisition of angiographic and hemodynamic data sought by the operating physician.

**Radiation measurements.** Radiation parameters collected included cumulative air kerma (AK) expressed in milliGray (mGy), measured at the interventional reference point, determined by the imaging system, cumulative dose-area product (DAP) expressed in Gray centimeter squared (Gy cm<sup>2</sup>) and fluoroscopy time (FT) in minutes. Flat-panel cardiac catheterization laboratory equipment (Allura, Philips Healthcare, Andover, Massachusetts) was used for the procedures. Hardware and software for measurement of AK and DAP built in the x-ray unit were used. The number of acquired cineangiograms was recorded. Fluoroscopy and cine-angiography were performed at 15 frames/s.

**Operator radiation exposure.** Operator radiation exposure was measured using a wearable personal dosimeter using ion-chamber technology (Instadose, Mirion Technologies, Irvine, California), worn outside the lead apron, in the trunk pocket, by the operator. Operator



dose was recorded at the termination of the procedure. Measurements were expressed in millirem (mrem).

**Operator experience data.** Data on operator experience in performing transradial procedures were collected. Operator experience was categorized as “low” if operators had successfully completed 100 to 500 transradial procedures (combined diagnostic interventional procedures) in their career, “medium” if 501 to 999 transradial procedures in their career, and “high” if >1,000 transradial procedures in their career before participation in the trial. Operators with experience of <100 transradial procedures were not allowed to participate in the trial. Five operators performed all procedures included in the study. The number of total, transradial, and transfemoral procedure volumes for the study center and each operator are detailed in the [Online Appendix](#).

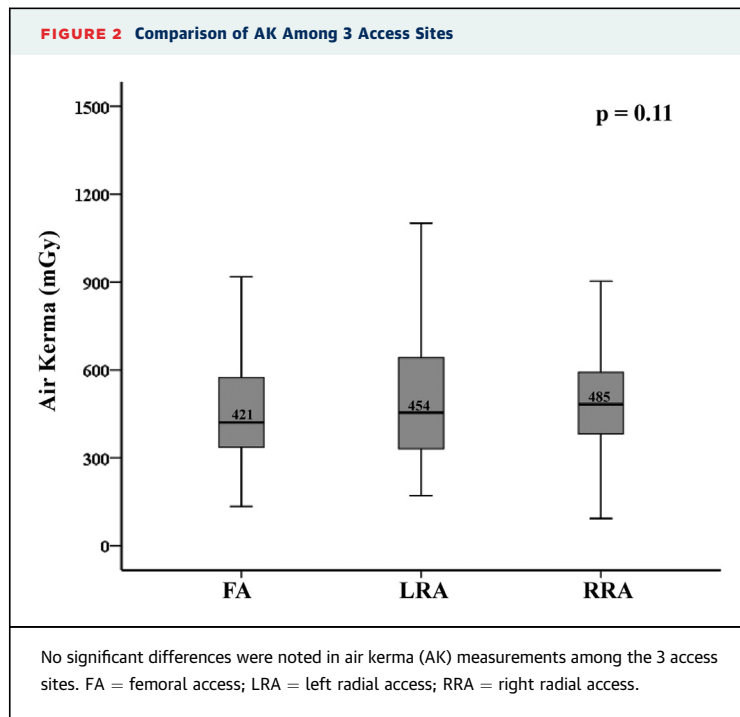
**Statistical analysis and sample size calculation.** Sample size calculation was performed using 1-way analysis of variance to detect differences in the primary outcome variable of AK among the FA, LRA, and RRA groups. As there are no previously published data on AK differences among FA, LRA, and RRA access coronary angiography, we used an a priori assumption for mean AK in groups FA, LRA, and RRA based on our retrospective review of 1,000

procedures. On the basis of these observations, we assumed mean AK values of  $420 \pm 150$  mGy for FA,  $500 \pm 155$  mGy for LRA, and  $460 \pm 165$  mGy for RRA, respectively. A noninferiority design was chosen with a 2-sided alpha error of 0.01 (after Bonferroni correction factor of 3 due to 3 comparisons, i.e., FA with RRA, LRA with RRA, and FA with LRA) and a power of 0.8. A sample size of 490 patients per group

**TABLE 2 Demographic, Procedural, and Radiation Parameters**

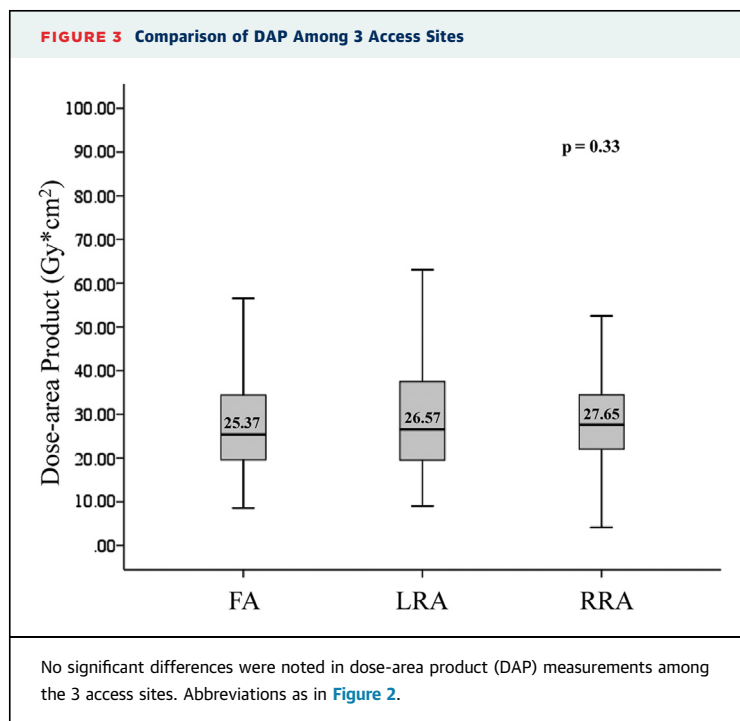
	Femoral (n = 498)	Left Radial (n = 498)	Right Radial (n = 497)	p Value
Age, yrs	57 (47-79)	57 (54-65)	61 (55-66)	0.38
Male	388 (78)	383 (77)	363 (73)	0.10
Hypertension	292 (58)	305 (61)	316 (64)	0.22
Diabetes	162 (32)	180 (36)	177 (36)	0.37
Height, cm	164 (158-169)	163 (158-169)	163 (158-169)	0.15
Weight, kg	65 (60-70)	64 (59-70)	65 (61-70)	0.47
Number of catheters	2 (2-2)	2 (2-2)	1 (1-2)	0.0001
Number of cine runs	9 (8-11)	10 (9-11)	10 (9-12)	0.0001
Air kerma, mGy	421 (337-574)	454 (330-643)	485 (382-592)	0.11
DAP, Gy cm <sup>2</sup>	25.4 (19.6-34.4)	26.6 (19.5-37.5)	27.7 (22.0-34.5)	0.33
Fluoroscopy time, min	1.3 (1-1.7)	1.3 (1-1.7)	1.32 (1-1.7)	0.18
Operator dose, mrem	2 (2-4)	3 (2-5)	3 (2-3)	0.0001

Values are median (interquartile range) or n (%).  
 DAP = dose-area product.



was deemed sufficient to detect a mean difference in AK of 40 mGy between the closest groups (in this analysis, FA and RRA).

Kolmogorov-Smirnov analysis was performed to evaluate the distribution of each variable that was analyzed. Categorical variables were analyzed using chi-square test, and continuous variables were



analyzed using analysis of variance for normally distributed variables and Kruskal-Wallis test for variables with distributions that were not normal. Hierarchical linear regression was used to identify independent predictors of AK, entering control variables found to be significantly associated with AK on univariate analysis in the first stratum, and operator experience as an independent variable in the second stratum. Primary and secondary endpoints were compared across the groups using an intent-to-treat analysis. A pre-specified analysis of the 3 access site cohorts was planned to study the association of procedural variables, operator experience, and primary outcome variable AK in these subcohorts. A separate analysis of association between AK and operator experience was performed in the femoral cohort. All analyses were performed using SPSS software (version 17.0, SPSS Inc., Chicago, Illinois).

## RESULTS

### STUDY SAMPLE AND BASELINE CHARACTERISTICS.

Between August 1, 2012 and November 30, 2013, 1,919 patients presenting for cardiac catheterization at Seth N.H.L Municipal Medical College, V.S. General Hospital were screened for the study. Patients with a history of previous coronary artery bypass graft surgery (n = 142) were excluded. Patients with comorbidities compromising the use of right radial artery, left radial artery, or femoral artery, such as dialysis access (n = 29), previous axillary node dissection (n = 15), known forearm vascular abnormality (n = 5), and occlusive aorto-iliac disease (n = 14) were excluded. Patients undergoing ad hoc percutaneous coronary intervention (PCI) (n = 221) were excluded, due to the inherent procedural heterogeneity in PCI procedures that may affect radiation parameters. Five operators randomized 1,493 patients undergoing diagnostic cardiac catheterization to the FA (n = 498), LRA (n = 498), or RRA (n = 497) groups. The randomization chart is shown in Figure 1. Demographic, procedural, and radiation variables comparing the 3 groups are shown in Table 2. No significant difference in age, height, and weight was found among the 3 groups.

**Procedural outcomes.** All procedures were successfully completed. Access site crossover occurred in 20 patients with 6 patients requiring right radial to left radial artery crossover, 8 patients requiring left radial to right radial artery crossover, 3 patients with crossover from right radial to femoral access, and 3 patients with crossover from left radial to femoral access. The number of catheters used was significantly higher in the LRA and FA groups than in the RRA group. Eighty-nine percent of RRA patients

had their procedure completed using a single catheter. The median number of cine angiograms acquired was significantly lower in the FA group than in the LRA group (9 [interquartile range (IQR): 8 to 11] vs. 10 [IQR: 9 to 11],  $p = 0.005$ ) and in the LRA group than in the RRA group (10 [IQR: 9 to 11] vs. 11 [IQR: 9 to 14],  $p = 0.0001$ ) (Table 2).

**Primary endpoint results.** There was no statistically significant difference in the primary endpoint of AK among the 3 access sites (median: FA: 421 mGy [IQR: 337 to 574 mGy], LRA: 454 mGy [IQR: 331 to 643 mGy], and RRA: 483 mGy [IQR: 382 to 592 mGy],  $p = 0.146$ ) (Figure 2).

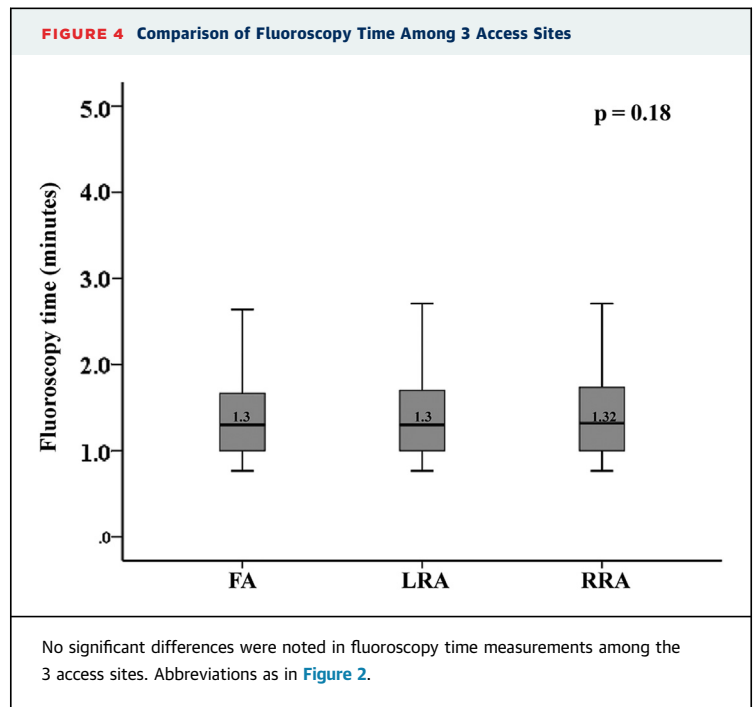
**Secondary endpoint results.** No significant difference was observed in DAP (medians: FA: 25.5 Gy cm<sup>2</sup> [IQR: 19.6 to 34.5 Gy cm<sup>2</sup>], LRA: 26.6 Gy cm<sup>2</sup> [IQR: 19.5 to 37.5 Gy cm<sup>2</sup>], and RRA: 27.7 Gy cm<sup>2</sup> [IQR: 21.9 to 34.4 Gy cm<sup>2</sup>],  $p = 0.40$ ) and FT (medians: FA: 1.3 min [IQR: 1.0 to 1.7 Gy cm<sup>2</sup>], LRA: 1.3 min [IQR: 1.0 to 1.7 Gy cm<sup>2</sup>], and RRA: 1.32 min [IQR: 1.0 to 1.7 Gy cm<sup>2</sup>],  $p = 0.19$ ) among the 3 access sites (Figures 3 and 4).

Operator exposure was similar in the FA and RRA groups (medians: FA: 2 mrem [IQR: 2 to 4 mrem], RRA: 3 mrem [IQR: 2 to 5 mrem],  $p = 0.72$ ). However, median operator exposure in the LRA group was significantly higher than in the other 2 access site groups (3 mrem [IQR: 2 to 5 mrem],  $p = 0.001$  vs. FA, and  $p = 0.0001$  vs. RRA) (Figure 5).

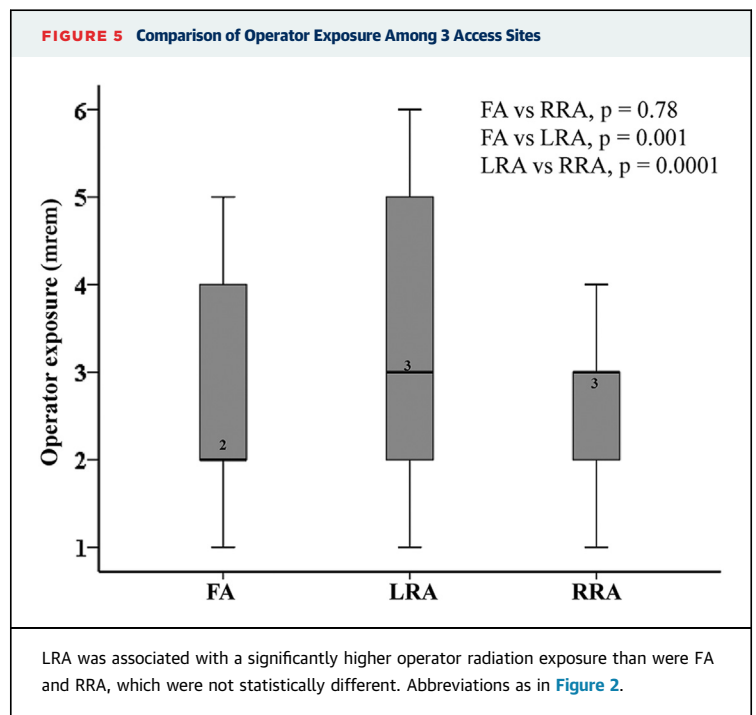
**Predictors of air kerma.** Univariate analyses showed weak but significant associations between AK and age ( $r = -0.141$ ,  $p = 0.0001$ ), sex (median: men: 471 mGy [IQR: 354 to 829 mGy] vs. women: 401 mGy [IQR: 297 to 543 mGy],  $p = 0.0001$ ), diabetes mellitus (mean-rank: 728 nondiabetics vs. 782 diabetics,  $p = 0.02$ ), height ( $r = 0.125$ ,  $p = 0.0001$ ), weight ( $r = 0.22$ ,  $p = 0.0001$ ), number of angiograms ( $r = 0.38$ ,  $p = 0.0001$ ), number of catheters used (chi-square: 7.8,  $p = 0.018$ ), and physician experience (chi-square: 417,  $p = 0.0001$ ).

Hierarchical multivariable linear regression analysis identified the number of cine angiograms ( $t = 19.2$ ,  $p = 0.0001$ ), number of catheters used ( $t = 3.2$ ,  $p = 0.001$ ), sex ( $t = -2.2$ ,  $p = 0.034$ ), age ( $t = -5.8$ ,  $p = 0.0001$ ), body weight ( $t = 3.9$ ,  $p = 0.0001$ ), and diabetes mellitus ( $t = 2.2$ ,  $p = 0.024$ ) as independent predictors of AK in the first stratum. Operator experience was entered in the model as an independent variable in the next stratum. Age, weight, number of cineangiograms, number of catheters, and diabetes mellitus continued to be significant independent predictors of AK. Operator experience was identified as an independent predictor of AK ( $t = -7.9$ ,  $p = 0.0001$ ) after adjusting for above-mentioned independent variables.

Patient and procedural characteristics categorized by operator experience are shown in Table 3. There



were 632 procedures performed by 2 operators in the low-experience category, 428 procedures by 2 operators in the medium-experience category, and 433 procedures by 1 operator in the high-experience category. Despite performing the procedure on a less complex subset as evidenced by a cohort with younger and taller patients and fewer women, operators with



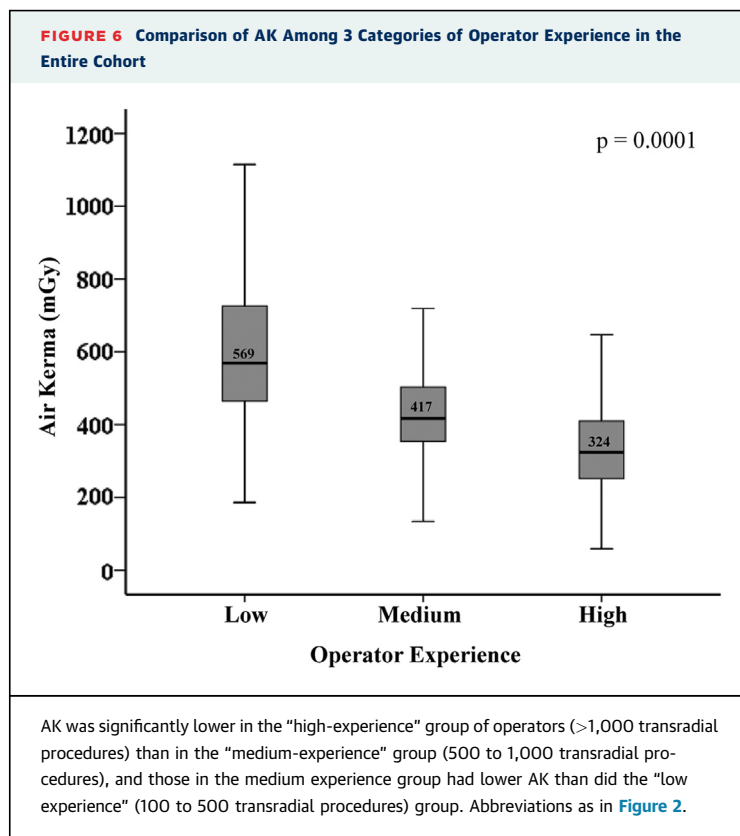
**TABLE 3 Patient and Procedural Characteristics Categorized by Operator Experience**

	Low Experience (n = 632)	Medium Experience (n = 428)	High Experience (n = 433)	p Value
Age, yrs	56 (50-65)	62 (53-73)	62 (54-70)	0.0001
Height, cm	165 (160-170)	163 (158-168)	162 (156-167)	0.0001
Weight, kg	65 (60-70)	65 (61-71)	65 (59-72)	0.80
Male	520 (82)	319 (75)	296 (68)	0.0001
Procedures, n	632	428	433	0.0001
Number of catheters	2 (1-2)	2 (1-2)	2 (2-2)	0.0001
Number of cineangiograms	11 (10-14)	9 (9-11)	9 (8-9)	0.0001
Air kerma, mGy	569 (465-726)	417 (354-503)	324 (252-410)	0.0001
Air kerma/run, mGy	56 (41-68)	44 (38-49)	37 (32-40)	0.0001
DAP, Gy cm <sup>2</sup>	32.99 (27.04-43.1)	24.72 (20.48-29.79)	19.18 (14.91-25.21)	0.0001
Fluoroscopy time, min	1.4 (1-2.1)	1.3 (1-1.6)	1.2 (1-1.5)	0.0001
Operator exposure, mrem	3 (3-5)	2 (2-2)	2 (1-3)	0.0001

Values are median (interquartile range) or n (%), unless otherwise indicated.  
DAP = Dose-area product.

less experience had higher radiation burden with significantly higher AK, DAP, and FT. Operators with less experience recorded a significantly higher number of cineangiograms than did those with more experience (Table 3). Median AK decreased with increasing operator experience (Figure 6) with significant continuing reduction noted even when medium-experience operators were compared with high-experience operators (low experience: 569 mGy [IQR: 465

to 726 mGy], medium experience: 417.5 mGy [IQR: 354 to 503 mGy], and high experience: 324 mGy [IQR: 251 to 411 mGy], p = 0.0001). AK per cineangiographic run also decreased with increasing operator experience (median: 56 [IQR: 41 to 68] mGy/run in the low-experience operator group, 44 [IQR: 38 to 49] mGy/run in the medium to experience operator group, and 37 [IQR: 32 to 40] mGy/run in the high-experience operator group, p = 0.0001). The inverse relationship between AK and the operator’s radial experience was noted when the FA group was separately analyzed (medians: low experience: 568 mGy [IQR: 457 to 727 mGy], medium experience: 395 mG to y [IQR: 339 to 459 mGy], high experience: 327 mGy [IQR: 284 to 397 mGy], p = 0.0001) (Figure 7).



## DISCUSSION

The results of this randomized controlled study demonstrate that access site choice is not associated with significant difference in radiation exposure for patients undergoing coronary angiography. It also emphasizes that several other factors including patient age, sex, weight, and procedural variables, such as number of cineangiographic acquisitions, number of catheters needed to complete the procedure, and, importantly, operator experience are the predominant drivers of radiation exposure. These findings are similar to the findings of the radiation substudy of the RIVAL (Radial Versus Femoral Access for Coronary Intervention) trial, where in “no-PCI” procedures, no significant difference in AK was observed (13).

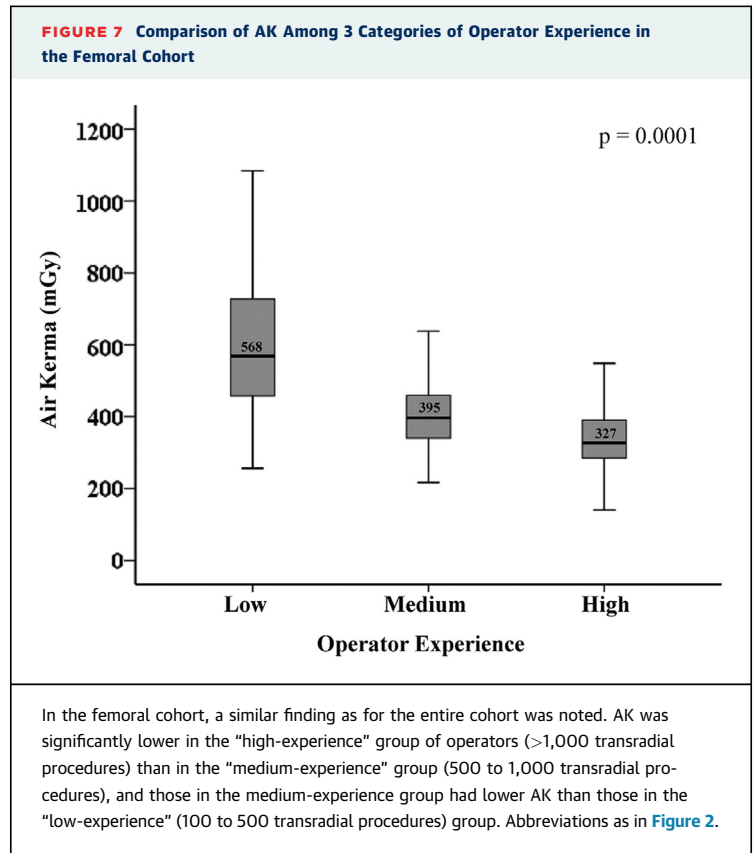
These data suggest that previously published data from observational studies showing higher radiation exposure with TRA are likely confounded by the influence of the covariates mentioned previously. Similar findings with operator experience and



radiation burden have been observed in other procedures involving the use of fluoroscopy and cine-radiography (14-16). Physicians in training have been noted to have longer FT compared with those with experience when using RRA (10). The learning curve for TRA is likely a composite of several domains, with the commonly proposed benchmark threshold of 50 to 100 procedures (17,18) probably marking the inflection point for variables such as procedural success, and FT. Recent data from a large registry has shown a 30 to 50 procedure threshold for reductions in FT and contrast volume, with a continuing reduction in these parameters observed as the operator accumulates a greater procedural experience (19). Our data corroborate the continuing reduction in radiation use, with increasing operator experience, with a downward trend continuing well past previously described levels of experience. A continuing training process with regard to radiation use is probably a result of attributes such as better catheter manipulation skills, resulting in shorter FT. The need to acquire fewer coronary artery cineangiograms as shown in our dataset, with likely better attention to duration and angulation of acquisitions, coning, and shielding, might be responsible for the observed reduction in AK in the most experienced group versus other groups. The inverse relationship between operator experience and the outcome measure was observed even in the transfemoral cohort, supporting the fact that the “radiation burden-operator experience” relationship exists regardless of access site used. These findings are reassuring as they indicate that the observations of higher radiation burden with TRA versus TFA in previous reports might well be a result of the learning process seen with almost every “skill”-requiring procedure, rather than an insurmountable issue with TRA.

This randomized trial did not reveal any difference in FT between LRA and RRA, as observed in earlier studies (10). In fact, LRA was associated with higher operator exposure, measured at the level of the operator’s thorax, compared with FA and RRA sites, likely because of the shorter distance between the operator (standing on patient’s right side) and the source of radiation and scatter while performing procedures using LRA, in a typical cardiac catheterization laboratory with a setup designed for the operator standing on the patient’s right side. These findings further underscore the importance of careful attention to duration of acquisition, angulation, operator’s distance from the radiation source, frame rate of x-ray output (20), and other procedural attributes, rather than access site choice in reducing patient and operator radiation exposure.

**STUDY LIMITATIONS.** Although our study was the first to compare the 2 radial artery access sites



independently with femoral artery access in a prospective randomized fashion, the protocol did not require the operators to follow a certain sequence or duration routine during cineangiography acquisitions, potentially adding to some procedural heterogeneity. A randomized comparison of these 3 access sites using a standardized acquisition duration and sequence of views of the coronary arterial system and left ventricle may further clarify the differences between radiation burden of procedures performed using these 3 access sites but could be challenging because of differences in individual patient coronary anatomy and body size. Also, the study could not be blinded, and hence effects of operator behavior based on access site allocation might have affected outcome measures such as radiation parameters. The analyses of association between operator experience and AK, although pre-specified, were limited, as patients were not randomized on the basis of operator experience. Finally, the FT observed in our study is significantly shorter than that in previous reports. These observations could be explained by the experienced operator mix in this study, as well as a younger cohort of study patients than in previous reports, likely associated with less subclavian tortuosity and other adverse anatomic attributes than in

previously reported datasets. The patients in our cohort were younger and weighed less than a typical Western patient, hence the lower radiation exposure, which may have attenuated the differences among the access sites. The very low crossover rate in our trial compared with that of previous reports may be a result of a highly skilled operator mix, and the “emigrative selection bias” introduced by exclusion of ad hoc PCI. Exclusion of PCI patients might also partly explain some of the discrepancy between our findings and previous randomized trials.

## CONCLUSIONS

There are no significant differences in AK, DAP, or FT among LRA, RRA, and FA when used by operators with sizeable experience using all 3 access sites. Increasing operator experience continues to improve radiation use for all access sites, including FA. Operator radiation exposure is likely a function of the operator’s distance from the radiation source and shielding, hence in a catheterization laboratory setup favoring right-sided procedures, it is higher with LRA.

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## PERSPECTIVES

**WHAT IS KNOWN?** Previous observational data have shown higher radiation exposure with TRA.

**WHAT IS NEW?** Our randomized controlled trial showed no significant difference in radiation burden among RRA, LRA, and FA coronary angiograms. Operator experience in performing radial access procedures was a significant predictor of radiation burden.

**WHAT IS NEXT?** Further trials with similar design to evaluate radiation burden in interventional procedures, preferably in a multicenter setting, are needed.

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**KEY WORDS** coronary angiography, operator experience, radiation exposure, transradial access

**APPENDIX** For the data on procedural details of the study center and the operators participating in the study, please see the online version of this paper.