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Operator radiation exposure during transradial coronary angiography

Effect of single vs. double catheters

Use of the radial artery for coronary angiography has been gaining popularity over the traditional femoral approach owing to the lower frequency of associated complications. However, the widespread use of this approach has had a setback because of the higher exposure of the operator to radiation [1–3].

Several investigators have made attempts to decrease the exposure of operators to radiation in the hope of reducing the risk of carcinogenesis and associated injuries. By adding an extension tube to the proximal part of the coronary catheter, Marque et al. were able to increase the distance between the operator and the source of X-rays, thereby reducing the operator radiation exposure [4]. In a similar context, different X-ray shields have been tested to decrease the dose of radiation that reaches the operator. The success associated with the use of these shields varies, with some investigators reporting a significant reduction in the dose of radiation exposure [5, 6] while others have found similar effects [7]. Interestingly, a study by Musallam and colleagues demonstrated increases in patient exposure to ionizing radiation when they used the shields to reduce the X-ray dose reaching the operator [8].

New generations of angiography catheters have been designed to be directed into either the left or right coronary arteries without needing to be changed [9, 10]. In addition to the ease of access to both coronary arteries, these catheters may potentially decrease the fluoroscopy time and the extent of radiation exposure of both the patients and the operators. In the traditional two-catheter approach (TCA), a JL3.5 catheter is used to access the left coronary artery and JR4.0 is used to direct the catheter into the right coronary artery during coronary angiography via a transradial approach. Recently, Tiger II (Terumo, Corporation, Tokyo, Japan) catheters are being used as a single catheter to access both the left and right coronary arteries via the right radial artery. To the best of our knowledge, no study to date has compared operator exposure to radiation with the single Tiger II catheter and with traditional TCA. We hypothesize that the use of a single-catheter approach (SCA) is associated with lower doses of radiation exposure for both the operators and the patients when compared with the TCA technique.

Patients and methods

The study design, protocol, and informed consent form were reviewed and approved by the Institutional Review Board for both scientific and ethical merit. The study included all consecutive elective transradial coronary angiographic examinations performed between April 2015 and September 2016. All patients with known peripheral arterial disease, absence of adequate ulnar artery perfusion in the Allen test, those in whom attempts to engage or cannulate the coronary arteries were unsuccessful, and those who refused to participate in the study were excluded. Moreover, patients with chronic kidney disease of stage 3 or higher (estimated glomerular filtration rate <60 ml/min/1.73 m^2) were excluded. We additionally excluded patients undergoing coronary angiography following coronary artery bypass grafting (CABG) surgery and those who suffered from valvular heart diseases.

After signing informed consent, patients were randomly allocated to the SCA approach with Tiger II or the TCA approach using JL3.5 and JL4.0 catheters. One-to-one randomization was performed with a computer software (RandList1.2) in blocks of four patients (**Fig. 1**). All staff members in the catheterization laboratory (including two registered nurses, one radiology technologist, and one interventional cardiologist) were not blinded to the randomization.

All procedures were done using the Axiom Artis dFC Model Cath Lab System (Siemens AG, Munich, Germany).

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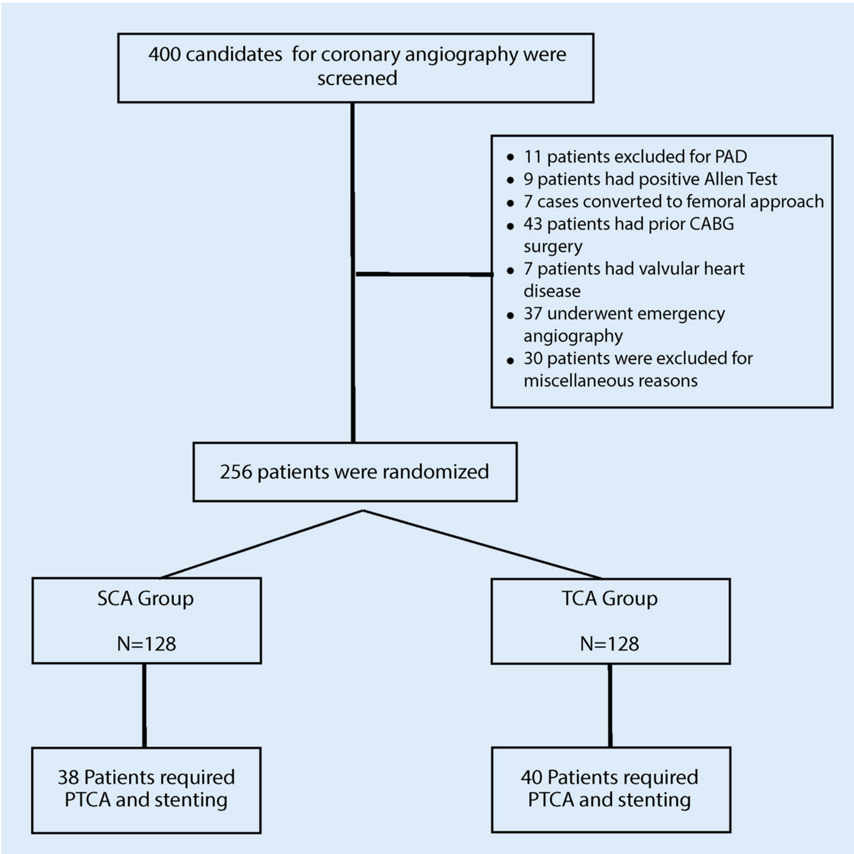

Fig. 1 ▲ Flow diagram depicting study design and list of exclusion criteria. *CABG* coronary artery bypass grafting, *PAD* peripheral arterial disease, *PTCA* percutaneous transcatheter coronary angioplasty, *SCA* single-catheter approach, *TCA* two-catheter approach

The angiography unit was controlled daily using DIA set X-ray QC kits (PTW, Freiburg, Germany) to assure the quality of radiation output (kVp_{max}, kVp_{mean}, PPV, time, and dose). Four standard views for the left coronary system included the right anterior oblique (RAO; cranial 15°/35°+ caudal 20°/25°) and left anterior oblique (LAO; cranial 40°/20° + caudal 50°/30°) positions. In addition, two standard views for the right coronary system included the LAO (cranial 30°/15°) and RAO (30°) positions for each angiogram. Imaging variables such as pulse rate (15 PPS), frame rate (15 FPS), size of magnification during fluoroscopy (25 cm), and image acquisition (20 cm) were kept the same for all angiographies.

The ALARA (as low as reasonably achievable) principles were used to protect the operator against radiation-induced injuries by both structural shields (ceiling-suspended lead shield and pivotal lead shield, 0.5 mm lead equivalent; MAVIG, Munich, Germany) and two-piece lead aprons with thyroid covers and lead-tinted glasses. The dose of the operator radiation exposure was measured with an electronic radiation dosimeter (Smart Rad; model EV-1, Type GM-Tube, Enviro Korea Co., Ltd., Seoul, Korea) that was attached to the breast pocket of the operator on the outside of the lead apron. The amount of ambient radiation was subtracted from the measured dose at the end of each procedure and was documented. The patient radiation exposure was measured by an integrated ionization chamber (Diametor, PTW, Freiburg, Germany) and reported as air kerma and dose–area product (DAP).

The right radial artery was accessed using the Seldinger technique in all patients and a 6.0-F sheath (Terumo, Somerset, N.J.) was advanced over a J-wire (0.035″× 153 cm). For the TCA group, JL3.5 and JR4.0 (Cordis™ Corp., Miami, Fla.) catheters were used to access the left and right coronary artery, respectively. In the SCA group, a single Tiger II (Terumo™ Corp., Tokyo, Japan) catheter was used to access both coronary arteries. In order to prevent radial artery spasm and occlusion, 2,000 U heparin and 100 µg nitroglycerine were administered through the sheath. Images were obtained following manual injection of Omnipaque 350 mg/ml using a 10-cc syringe. The total time of the procedure was defined as the time lapsed from the injection of local anesthetic to the removal of the last diagnostic catheter and all measurements were recorded at this time point. Abnormal anatomy was defined as any abnormality in the origin of the coronary ostia in relation to the cusps of the aortic valve.

Statistical analysis

Radiation exposure to the operator was the primary endpoint of this study. In order to determine the sample size, we set the average dose of radiation reported for the operator exposure at 30–35 µSv for simple coronary angiographies and 50–60 µSv for procedures requiring additional interventions [11, 12]. The operator dose of radiation exposure is in the range of 30.0 ± 12.0 µSv at our institute. Clinical significance was defined as at least 20% reduction in exposure of the operator to the ionizing radiation during simple coronary angiography. Power analysis was performed using online software available from the University of British Columbia. A sample size of 63 procedures was needed in each study arm to obtain an alpha error of 0.05 and a power of 80%. Data were analyzed using SPSS 24.0 (IBM Corp., Chicago, Ill.). Numerical data were analyzed with independent-samples *t* tests and the results are presented as mean ± SD. Categorical data were analyzed using the chi-square test and the results are presented as frequency and percentages. A multivariate linear regression model was constructed using the operator dose as the dependent variable and the SCA or TCA was used as independent variable along with other confounding variables. Null hypotheses were rejected if p values were less than 0.05.

Abstract · Zusammenfassung

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Operator radiation exposure during transradial coronary angiography. Effect of single vs. double catheters

Abstract

Background. The right radial artery has gained popularity as the preferred access site for coronary angiography. To save time and limit the radiation exposure of operators and patients, newly designed catheters can be used to access both the right and left coronary arteries. The aim of this study was to compare operator radiation exposure between single-catheter (SCA) and two-catheter approaches (TCA).

Methods. In all, 256 patients undergoing diagnostic coronary angiography via the right radial artery in a high-volume medical center were randomized to either the SCA or TCA group. The dose of radiation exposure of the operators was measured by an electronic dosimeter attached to the breast pocket of the operator's apron. The dose–area product and air kerma were used as indices of patient exposure to radiation. The duration of fluoroscopy "beam-on" time, acquisition time, and total duration of the procedure were measured and analyzed for the two groups.

Results. Operator radiation exposure was 21.6 ± 11.4 µSv in the SCA group, which was significantly less than 28.0 ± 14.9 µSv in the TCA group. The duration of fluoroscopy was significantly shorter in the SCA group than in the TCA group (152 ± 83 vs. 203 ± 121 s; $p < 0.001$). Moreover, the total duration of the diagnostic procedure was also shorter in the SCA group compared with the TCA group (9.5 ± 3.2 vs. 11.4 ± 4.0 min; $p < 0.001$).

Conclusion. The use of SCA is advantageous over TCA in reducing the exposure of operators to radiation. The shorter duration of fluoroscopy beam-on time and total procedure time may contribute to the lower exposure of operators to radiation.

Keywords

Coronary angiography · Radiation exposure · Radial artery · Catheterization · Fluoroscopy

Strahlenexposition des Untersuchers bei transradialer Koronarangiographie. Einfluss von Einzel- vs. Doppelkatheter

Zusammenfassung

Hintergrund. Die rechte A. radialis wird zunehmend als bevorzugte Zugangsstelle für die Koronarangiographie verwendet. Um Zeit zu sparen und die Strahlenexposition von Untersuchern und Patienten zu begrenzen, können neu entwickelte Katheter für den Zugang sowohl zur rechten als auch zur linken Koronararterie eingesetzt werden. Ziel der vorliegenden Studie war es, die Strahlenexposition des Untersuchers zwischen Einzelkatheter- und Doppelkathetereinsatz zu vergleichen.

Methoden. Insgesamt wurden 256 Patienten, bei denen eine diagnostische Koronarangiographie über die rechte A. radialis in einem medizinischen Zentrum mit hohem Durchsatz erfolgte, randomisiert entweder der Einzel- oder der Doppelkathetergruppe zugeteilt. Mit einem elektronischen Dosimeter, das an der Brusttasche der Untersucherschürze befestigt war, wurde die Dosis der Strahlenexposition des Untersuchers gemessen. Das Dosis-Flächen-Produkt und die Luftkerma wurden als Indizes der Strahlenexposition des Patienten verwendet. Für beide Gruppen wurden die Dauer der Durchleuchtungszeit mit eingeschaltetem Röntgenstrahl, die Aufnahmedauer und die Gesamtdauer der Untersuchung erfasst und ausgewertet.

Ergebnisse. Die Strahlenbelastung des Untersuchers betrug in der Einzelkathetergruppe 21,6 ± 11,4 µSv und war somit signifikant geringer als der Wert von 28,0 ± 14,9 µSv in der Doppelkathetergruppe. Auch war die Durchleuchtungsdauer in der Einzelkathetergruppe signifikant kürzer als in der Doppelkathetergruppe (152 ± 83 vs. 203 ± 121 s; $p < 0{,}001$). Außerdem war auch die Gesamtdauer der Untersuchung in der Einzelkathetergruppe kürzer als in der Doppelkathetergruppe (9,5 ± 3,2 vs. 11,4 ± 4,0 min; $p < 0{,}001$).

Schlussfolgerung. Die Verwendung von Einzelkathetern ist gegenüber dem Einsatz von Doppelkathetern vorteilhaft, da so die Strahlenexposition des Untersuchers verringert ist. Zur geringeren Strahlenexposition der Untersucher tragen möglicherweise auch die kürzere Dauer der Durchleuchtungszeit mit eingeschaltetem Röntgenstrahl und der Gesamtuntersuchungszeit bei.

Schlüsselwörter

Koronarangiographie · Strahlenexposition · A. radialis · Katheteruntersuchung · Durchleuchtung

Results

This study included 164 men and 92 women undergoing transradial coronary angiography. The average age of the patients was 59.4 ± 10.8 years. Body mass index was 27.5 ± 4.5 kg/m^2. In all, 170 patients presented with chronic myocardial ischemia and stable angina while 86 patients had acute coronary syndrome at the time of coronary angiography. Anomalies were detected in the origin of the coronary ostia in 18 patients, while the remaining 238 patients reportedly had normal coronary anatomy. The most common type of coronary abnormality (10 out of 18 cases) was ectopic left circumflex artery originating from the right sinus of the aorta. An ectopic right coronary artery originating from the left aortic sinus was detected in six patients. The least common form of abnormality was the presence of ectopic left anterior descending artery originating from the right aortic sinus, which was observed in two patients. The prevalence of coronary abnormalities was similar between the SCA group and the TCA group. Coronary intervention was required in 78 patients following the initial diagnostic procedure.

From a total of 256 patients, an equal number of patients were randomized to

Table 1 Comparison of demographic and clinical characteristics of patients in the SCA and TCA groups

		SCA ($N = 128$)	TCA ($N = 128$)	*p*
Gender	Male	82 (64.1%)	82 (64.1%)	1.000
	Female	46 (35.9%)	46 (35.9%)	
Age (years)		59.5 ± 11.5	59.2 ± 10.0	0.854
Height (cm)		165 ± 10	166 ± 9	0.265
Weight (kg)		74.5 ± 13.8	76.6 ± 12.0	0.204
Body mass index (kg/m^2)		27.3 ± 4.8	27.7 ± 4.2	0.446
Clinical presentation	ACS	46 (35.9%)	40 (31.3%)	0.508
	CSA	82 (64.1%)	88 (69.7%)	
Contrast media volume (ml)		51 ± 12	54 ± 16	0.049

Values are shown as mean ± SD for numerical variables and *N* (%) for nominal variables
ACS acute coronary syndrome, *CSA* chronic stable angina, *SCA* single-catheter approach, *TCA* two-catheter approach

Table 2 Comparison of fluoroscopy time and patient radiation exposure in the SCA and TCA groups

	SCA ($N = 128$)	TCA ($N = 128$)	*p*
Air kerma (mGy)	263 ± 171	294 ± 147	0.123
Acquisition time (s)	29.0 ± 8.2	28.7 ± 8.3	0.780
Total procedure time (min)	9.5 ± 3.2	11.4 ± 4.0	<0.001
Fluoroscopy time (s)	152 ± 83	203 ± 121	<0.001
Dose–area product (mGy*m^2)	1.93 ± 1.10	2.19 ± 1.08	0.059

Values are shown as mean ± SD for numerical variables

undergo coronary angiography using either the SCA or the TCA technique. There was no difference in gender distribution, age, body habitus, clinical presentation, or the frequency of abnormal coronary anatomy between the SCA and TCA groups (**Table 1**). Patients in the SCA group received lower volumes of contrast media (51 ± 12 ml) than those in TCA group (54 ± 16 ml; $p = 0.049$). Both procedure time (9.5 ± 3.2 min vs. 11.4 ± 4.0 min; $p < 0.001$) and total fluoroscopy time (152 ± 83 vs. 203 ± 121 s; $p < 0.001$) were shorter in the SCA group than in the TCA group (**Table 2**). DAP (an index of patient radiation exposure) was 1.93 ± 1.10 mGy*m^2 in the SCA group compared with 2.19 ± 1.08 mGy*m^2 in the TCA group, which was just short of significance. Moreover, there was no difference in acquisition time, air kerma (AK), and exposure of patients to radiation as measured by DAP between the SCA and TCA groups.

The operator radiation exposure did not correlate with the body habitus of the patient ($R = 0.075$; $p = 0.254$) or with the acquisition time ($R = 0.041$; $p = 0.515$). However, there was a direct correlation between operator radiation exposure and the duration of fluoroscopy time ($R = 0.321$; $p < 0.001$), total duration of the procedure ($R = 0.266$; $p < 0.001$), and the exposure level of the patients to the ionizing radiation ($R = 0.178$; $p = 0.004$). There was a linear correlation between the DAP, total duration of angiography, and operator radiation exposure, as shown in the scatter plots in **Fig. 2**. Additionally, the operator radiation exposure was not significantly affected by the gender of the patients (**Fig. 3a**) or by the nature of their clinical presentation at the time of coronary angiography (**Fig. 3d**). Total operator radiation exposure was higher when the procedure was performed on patients with anatomically abnormal coronary openings (**Fig. 3b**). However, operator radiation exposure was significantly lower with the SCA than with the TCA (21.6 ± 11.4 µSv vs. 28.0 ± 14.9 µSv; $p < 0.001$). Furthermore, LAO caudal (50°/30°) and RAO (30°) projections were associated with the highest and lowest operator radiation exposure, respectively, compared with other projections regardless of the use of the SCA or TCA technique (data not shown).

In a multivariate linear regression model, we examined the independent factors that might have contributed to the measured dose of operator exposure. Among all the independent factors listed in **Table 3**, duration of fluoroscopy, presence of abnormal anatomy, and the approach used for angiography were independent factors that contributed significantly to the operator radiation exposure. There was a strong trend indicating an average of 3.2 µSv increase in operator radiation exposure when coronary angiography was performed for patients with acute coronary syndrome. The amount of operator radiation exposure increased by 7.2 µSv if the patients had an abnormal take-off of the coronary arteries from the aortic root ($p = 0.025$). For every 1-min increase in the duration of fluoroscopy, the operator exposure increased by 1.2 µSv. Finally, the radiation exposure of the operator decreased by 4.3 µSv if the SCA was used for coronary angiography.

Discussion

We demonstrated that the SCA through the right radial artery was associated with a significantly lower dose of operator exposure to radiation compared with the traditional use of two catheters to access the left and right coronary arteries. We also showed that there was a direct correlation between the duration of coronary angiography, as well as the duration of fluoroscopy, and the exposure to radiation both by the patients and the operator. In multivariate analysis, we were able to demonstrate that use of the SCA was independently associated with lower operator exposure to radiation. As expected, the duration of the procedure – especially the duration of the time that the fluoroscopy beam was on – directly affected the extent of operator exposure to radiation.

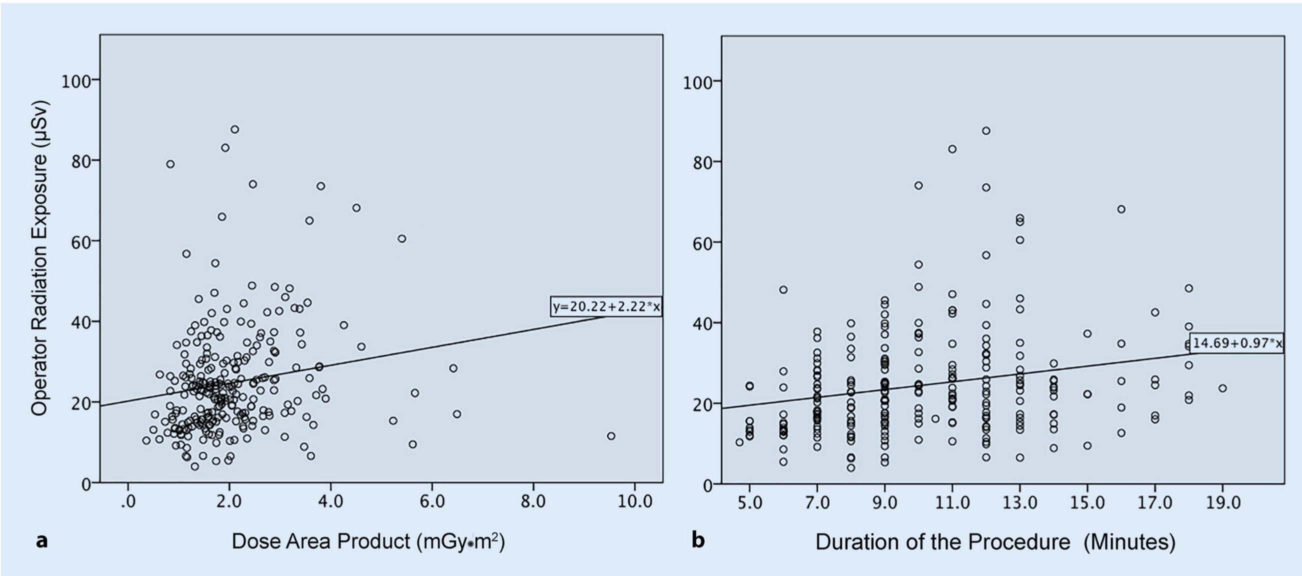

Fig. 2 ▲ Linear correlation between operator radiation exposure and dose–area product as an index of patient exposure (**a**) and total duration of the procedure (**b**)

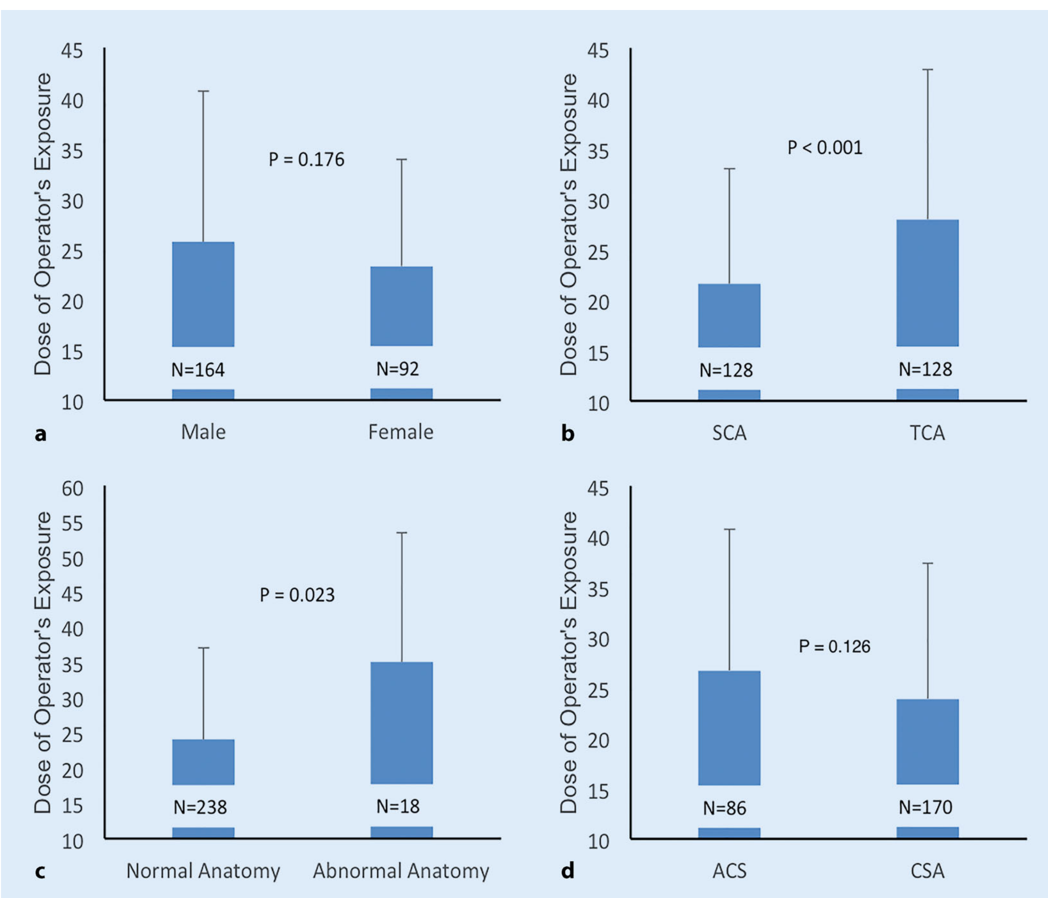

Fig. 3 ◀ The dose of operator radiation exposure compared between male and female patients (**a**), use of single-catheter approach (*SCA*) vs. two-catheter approach (*TCA*; **b**), normal vs. abnormal take-off of coronary ostia from the aortic root (**c**), and clinical presentation of the patients at the time of angiography – acute coronary syndrome (*ACS*) vs. chronic stable angina (*CSA*; **d**)

Table 3 Multivariate linear regression model with confounding variables affecting the dose of operator exposure to radiation[a]

	B	SE	*t*	*p*	95% CI	
Constant	4.04	6.91	0.58	0.560	−9.58	17.65
Gender (female/male)	−2.44	1.74	−1.40	0.162	−5.88	0.99
Body mass index (kg/m^2)	0.23	0.19	1.22	0.222	−0.14	0.61
Abnormal/normal anatomy	7.16	3.18	2.25	0.025*	0.90	13.43
Chronic stable angina/ACS	−3.26	1.71	−1.91	0.058	−6.62	0.11
TCA/SCA	4.25	1.63	2.61	0.010*	1.04	7.47
Air Kerma (mGy)	0.00	0.01	0.82	0.411	−0.01	0.01
Duration of the procedure (min)	0.34	0.27	1.26	0.208	−0.19	0.88
Fluoroscopy time (s)	0.02	0.01	2.52	0.012*	0.01	0.04

*Statistically significant difference
ACS acute coronary syndrome, *CI* confidence interval, *SCA* single-catheter approach, *TCA* two-catheter approach
[a]Single-catheter approach (SCA) or two-catheter approach (TCA) was forced into the equation

X-rays belong to the high-frequency and high-energy end of the electromagnetic spectrum that can damage tissue upon exposure by the release of hydroxyl radicals. The injurious effects of ionizing radiation are either dose dependent (deterministic effect) or dose independent (stochastic effect) [13]. The burns that are produced following prolonged exposure to ionizing radiation during diagnostic and therapeutic procedures are examples of the deterministic effects of radiation. Both patients and operators are susceptible to radiation-induced injuries, and therefore much effort has to be made to reduce the exposure level following any intervention procedure that necessities the use of fluoroscopy. Accordingly, each institution is mandated by several regulating bodies to establish a radiation safety committee. This committee is charged with periodically educating the operators of fluoroscopy systems, such as cardiac catheterization laboratories, on how to minimize the extent of radiation exposure to themselves and the patients undergoing these procedures.

Despite having a higher radiation exposure to the operator, the transradial approach has recently gained popularity over the transfemoral technique [14, 15]. Our results show that the use of SCA decreases the fluoroscopy "beam-on" time by up to 25%, consistent with the results of studies by Chen et al. and Kim et al. [16, 17]. Such a decrease in radiation time is very important in procedures such as angioplasty and for examinations of coronary artery anomalies that require a longer fluoroscopy time. Attempts have been made to reduce the exposure to radiation by limiting the duration of real-time fluoroscopy and the frequency of fluoroscopic imaging. In this context, reducing the fluoroscopy time along with using the left radial artery has been suggested in order to decrease the operator exposure dose [18].

In comparison with the right radial approach, accessing the left radial artery was associated with a 30% lower radiation absorbed by the patients and a decrease in the doses of radiation exposure to the operator [19–21]. However, this observation was later contradicted by the same group of investigators attributing the existing difference in exposure to the operators' level of experience [20, 22]. It should be noted that all comparisons between accessing the left and right radial arteries with respect to the extent of exposure to radiation have been made using the double-catheter technique. **Fig. 4** depicts a straight path for engaging a single catheter to both coronary ostia using the right radial approach, a technique that requires more maneuvering and accessing either the left radial or femoral arteries. In order to decrease operator radiation exposure, attempts have been made to increase the distance of the operator from the machine, to use protective shields, or to decrease the duration of fluoroscopy [5, 6, 23, 24]. Catheters previously used for transradial angiography were originally designed for transfemoral applications [25], while the anatomical difference between the two approaches is significant enough to demand for catheters with a more specific design [26]. Additionally, with the use of the right radial artery as the preferred site of access, new catheters have been designed to access both coronary arteries with a single catheter [9, 10].

In addition, the relatively longer duration of fluoroscopy in the radial techniques, compared with the femoral approach, is due to the winding course of the arm vessels. Frequent fluoroscopic real-time imaging is required to avoid the cerebral arteries, while advancing a catheter or a guide-wire to the aortic root. Therefore, the duration of fluoroscopy beam-on time would be understandably shorter with the use of SCA, since real-time fluoroscopy is performed only once to catheterize both coronary arteries [26].

There have been reports of skin injuries to patients after angiography due to the high radiation doses in these procedures [27, 28]. The results of the present study show that both air kerma and DAP are not significantly affected by the use of either the SCA or TCA technique. In contrast to DAP, air kerma is not affected by the size of the radiation field because of the determination of the point dose; therefore, it provides a better prediction of skin injury. A previous study that compared SCA with TCA methods failed to report on these parameters [16]. In the present study, the volume of contrast medium that was used in the SCA group was lower than that used for the TCA group, a finding that was not reported by Chen et al. [16]. Our results indicate that the volume of contrast media is approximately 3 ml less in the SCA group. Despite its statistical significance, this difference in amount of volume has no clinical significance and could be easily attributed to the need for priming additional catheters (TCA group) or the differences in using manual or auto-injector systems.

Another important finding of the present study is the decrease in the overall duration of the procedure. Although

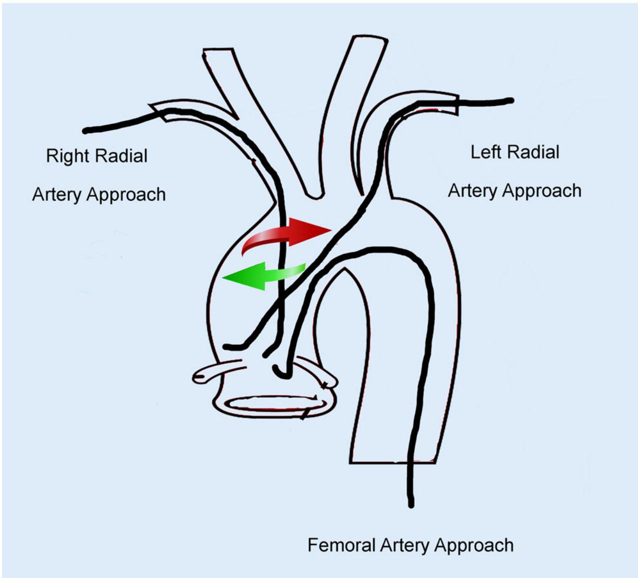

Fig. 4 ◂ Diagram depicting three popular access sites for performing coronary angiography. The right radial access site provides a relatively more direct access of both coronary arteries using a single catheter

faster completion of the procedure may potentially improve patient comfort level, the modest decrease observed in the relatively brief diagnostic procedures (9.5 min vs. 11.5 min) is unlikely to affect patient satisfaction in the long run. Moreover, patients are more likely to receive heparin in longer procedures, which may in turn increase the odds of bleeding complications. More importantly, our data indicate that the duration of the procedure correlates directly with the total operator exposure dose as well as the amount of radiation absorbed by the patient. Therefore, even modest reductions in the duration of the procedure are likely to decrease deterministic injuries to patients and operators and reduce the risk of stochastic injuries in the long term.

Conclusion

We conclude that in addition to utilization of X-ray shields and other personal protective devices, increasing the operator's distance from the X-ray tube and decreasing fluoroscopy beam-on time are still highly effective ways of reducing the exposure of the operator to radiation. Employing the SCA effectively shortens the duration of the procedure and minimizes fluoroscopy beam-on time during diagnostic coronary angiography, thereby reducing the operator's exposure to ionizing radiation. Although the patient radiation exposure did not reach a level of significance in this study, using the single-catheter technique in longer procedures for coronary interventions may favorably decrease the degree of patient exposure to radiation.

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Compliance with ethical guidelines

Conflict of interest. A. Tarighatnia, L. Pourafkari, A. Farajollahi, A.H. Mohammadalian, M. Ghojazadeh, and N.D. Nader declare that they have no competing interests.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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