# Clinical Investigation

# Randomized Noninferiority Trial of Radiation Exposure During Coronary Angiography: the Transradial and Transfemoral Approach by EXPERienced Operators in Daily rouTine (EXPERT) Trial

Cristiano de Oliveira Cardoso, MD, PhD<sup>1,2</sup>; Cláudio Vasques de Moraes, MD<sup>1</sup>; Julio Vinícius Teixeira, MD<sup>1</sup>; Carlos Roberto Cardoso, MD<sup>1</sup>; Felipe Baldissera, MD<sup>1</sup>; Eduardo Ilha de Mattos, MD<sup>1</sup>; Marcio José Siqueira, MD<sup>1</sup>; Leandro Fischer, BS<sup>1</sup>; Juliana Cañedo Sebben, MSc<sup>1</sup>; Bruna Santos Silva, BS<sup>1</sup>; Gabriel Broetto, BS<sup>1</sup>; Carlos Antônio Mascia Gottschall, MD, PhD<sup>1,2</sup>; Rogério Sarmento-Leite, MD, PhD<sup>1,2</sup>

## **Abstract**

**Background:** The transradial approach (TRA) to coronary angiography reduces vascular complications but is associated with greater radiation exposure than the transfemoral approach (TFA). It is unknown whether exposure remains higher when TRA is performed by experienced operators.

**Methods:** Patients were randomly, prospectively assigned to TRA or TFA. The primary end point was patient radiation dose; secondary end points were the physician radiation dose and 30-day major adverse cardiac event rate. Coronary angiography was performed by experienced operators using a standardized protocol.

**Results:** Clinical and procedural characteristics were similar between the TRA (n = 150) and TFA (n = 149) groups, and they had comparable mean (SD) radiation doses for patients (616.51 [252] vs 585.57 [225] mGy; P = .13) and physicians (0.49 [0.3] vs 0.46 [0.29] mSv; P = .32). The mean (SD) fluoroscopy time (3.52 [2.02] vs 3.13 [2.46] min; P = .14) and the mean (SD) dose area product (35,496.5 [15,670] vs 38,313.4 [17,764.9] mGy·cm²; P = .2) did not differ. None of the following factors predicted higher radiation doses: female sex (risk ratio [RR], 0.69 [95% CI, 0.38-1.3]; P = .34), body mass index >25 (RR, 0.84 [95% CI, 0.43-1.6]; P = .76), age >65 years (RR, 1.67 [95% CI, 0.89-3.1]; P = .11), severe valve disease (RR, 1.37 [95% CI, 0.52-3.5]; P = .68), or previous coronary artery bypass graft (RR, 0.6; 95% CI, 0.2-1.8; P = .38).

**Conclusion:** TRA for elective coronary angiography is noninferior to TFA when performed by experienced operators.

Keywords: Coronary angiography; radiation exposure; femoral artery; radial artery

## Introduction

he transradial approach (TRA)<sup>1</sup> is widely used in several countries<sup>2,3</sup> for diagnostic coronary angiography (CA) and percutaneous coronary intervention.<sup>4</sup> Compared with the transfemoral approach (TFA), TRA significantly reduces access-related bleeding,<sup>5</sup> entry-site complications,<sup>6</sup> and patient discomfort with early ambulation.<sup>7,8</sup>

Citation: de Oliveira Cardoso C, Vasques de Moraes C, Teixeira JV, Cardoso CR, Baldissera F, de Mattos El, Siqueira MJ, Fischer L, Sebben JC, Santos Silva B, Broetto G, Gottschall CAM, Sarmento-Leite R. Randomized noninferiority trial of radiation exposure during coronary angiography: the transradial and transfemoral approach by EXPERienced operators in daily rouTine (EXPERT) trial. *Tex Heart Inst J.* 2023;50(2):e227930. doi:10.14503/THIJ-22-7930

Corresponding author: Cristiano de Oliveira Cardoso, MD, PhD, Center for Preclinical Surgical & Interventional Research, Texas Heart Institute, 6770 Bertner Avenue, MC 1-268, Houston, TX 77030 (ccardoso@texasheart.org)

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<sup>&</sup>lt;sup>1</sup>Cardiology Institute, Rio Grande do Sul/University Foundation of Cardiology (IC-FUC), Department of Invasive Cardiology and Hemodynamics, Porto Alegre, Rio Grande do Sul, Brazil

<sup>&</sup>lt;sup>2</sup>Graduate Program in Health Sciences (Cardiology - PPG), University Foundation of Cardiology, Porto Alegre, Rio Grande do Sul, Brazil

Although TRA provides important benefits, 9,10 small randomized trials 11 and observational studies 12 have shown that procedures performed using TRA expose healthcare workers and patients to higher levels of ionizing radiation than TFA. However, because the RadIal Vs femorAL access for coronary intervention (RIVAL) 13 randomized trial showed that the efficacy of radial access might be linked to the operators' expertise and volume, it is possible that the higher radiation dose associated with TRA could be related more to operator skill than to the technique itself.

The objective of this study is to determine whether TRA for CA—when performed by experienced operators in daily practice—exposes patients and healthcare workers to higher levels of radiation than TFA.

## **Patients and Methods**

The institutional review board approved the protocol before screening and recruitment began (UP 4786/12). The Transradial and Transfemoral Approach by EXPE-Rienced Operators in Daily rouTine (EXPERT) Trial Executive Committee was responsible for all aspects of the study and reviewed all outcomes and complications. The study is registered at ClinicalTrials.gov (identifier NCT01794325).

#### **Trial Design**

The EXPERT trial was a randomized noninferiority trial comparing TRA and TFA for diagnostic CA (Fig. 1).

## **Participants**

Patients with suspected coronary artery disease and a clinical indication for CA were invited to participate. The inclusion criteria were indications for elective diagnostic CA, eligibility for either TRA or TFA, and age 21 years or older. Patients were excluded if they were scheduled for therapeutic procedures; underwent urgent or emergency procedures or simultaneous right-sided catheterization; had end-stage renal disease; or required additional, noncoronary angiography during CA.

#### **Interventionalist Expertise**

All procedures were performed by experienced interventional cardiologists who fulfilled the following criteria: (1) full training in both radial and femoral access for coronary diagnostic and therapeutic procedures, (2) completion of a minimum of 500 diagnostic proce-

## **Abbreviations and Acronyms**

AP anteroposterior
BR background radiation
CA coronary angiography
CABG coronary artery bypass graft
CC conversion coefficient
DAP dose area product
ED effective dose

EXPERT Transradial and Transfemoral Approach by EXPERienced Operators in Daily rouTine GUSTO Global Utilization of Streptokinase and

Tissue plasminogen activator in Occluded

arteries

kerma kinetic energy released per unit of mass

LAO left anterior oblique

mGy milligray
PD procedure dose
RAO right anterior oblique

REVERE Randomized Evaluation of Vascular Entry

site and Radiation Exposure

RIVAL Radial Vs femorAL access for coronary

intervention

RR risk ratio

SCAI Society for Cardiovascular Angiography &

Interventions

TFA transfemoral approach
TRA transradial approach

dures in the past 2 years, and (3) level III competency according to Society for Cardiovascular Angiography & Interventions (SCAI) guidelines. <sup>14</sup> Level III competency indicates an ability to perform complex interventional procedures, even in patients with challenging limb anatomy (eg, chronic total occlusion, multivessel disease) or acute myocardial infarction.

## **Imaging Protocol**

After screening was completed and patients provided written informed consent, they were randomly assigned to either TRA or TFA. In both groups, at least 9 prespecified basic views per patient were required (5 runs in the left coronary artery, 3 in the right coronary artery, and 1 in the left ventricle). Images were obtained at various angulations, in the following sequence: left ventriculography (right anterior oblique [RAO] 30° with no caudal or cranial angulation), left coronary (RAO 20°/caudal 20°, anteroposterior [AP] caudal 20°, left anterior oblique [LAO] 40°/caudal 30°, LAO 40°/cranial 25°, AP cranial 40°), and right coronary (LAO 30°, LAO 30°/cranial 30°, RAO 30°). Additional views were allowed if they were necessary for an accurate diagnosis. Appropriate use of edge filters, collimators, and flat detectors

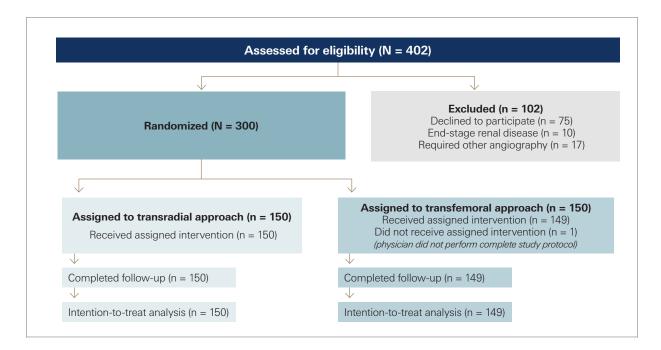


Fig. 1 Trial flow chart.

close to the patient's chest was required. All procedures were performed using low-dose fluoroscopy guidance (maximum radiation exposure, 50 milligray [mGy]/min) at a capture rate of 15 frames/s. Coronary images were acquired at a magnification of 20 cm, and left ventricular images were acquired at a magnification of 25 cm. Operators wore complete radiation protection gear (ie, a lead apron, leaded glasses, and upper- and lower-body shields).

Although patients with certain conditions were excluded from the study, those with a history of coronary artery bypass graft (CABG) and severe valvular heart disease were eligible to participate. For patients with previous CABG who were assigned to TRA, the right or left radial artery could be used according to the operator's discretion. Imaging acquisition included the 9 basic angiographic views described above plus 2 additional recommended runs per graft. Procedures in patients with severe valvular heart disease were performed with the 9 prespecified views. For patients with severe aortic stenosis, for example, operators were encouraged to cross the valve, perform left ventriculography, and measure the transaortic pressure gradient.

#### **Procedures**

**TRA.** Patients were supine with their arms at their sides; a sterile drape was placed. Local anesthetic (3-5

mL of 2% lidocaine) was injected subcutaneously, 2 cm proximal to the styloid process, over the palpable radial artery. The artery was punctured with a 22-gauge needle, and a 0.035-inch guidewire was inserted into the vessel. A small skin incision was made, and a 5F or 6F radial sheath (Radifocus Introducer II Standard Kit A; Terumo Interventional Systems) was introduced. Nitroglycerin (100-300 µg) was administered to induce vasodilation, and a bolus of heparin (5,000 units) was given intravenously to all patients after the guidewire reached the ascending aorta. Either a 5F or 6F catheter was used for CA; the catheter shape was selected according to operator discretion. The sheath was removed immediately after the procedure, regardless of the patient's level of anticoagulation, and a compression dressing was applied. Four hours later, the compression bandage was removed. Patients were discharged from the hospital on the same day.

**TFA.** Femoral access was obtained using traditional technique. A sterile drape was placed, and local anesthetic (10 mL of 2% lidocaine) was injected subcutaneously into the inguinal area. Femoral puncture was performed primarily using palpation of the inguinal ligament for guidance; if needed, fluoroscopic guidance was used. All operators were advised to perform the anterior wall puncture technique only. Either 5F or 6F introducers (Avanti+; Cordis) and catheters were used

according to the operator's discretion. The sheath was removed immediately after the end of the procedure, and manual compression was applied for hemostasis. No dedicated closure devices were used.

**Sedation.** For all patients (TRA and TFA groups), mild sedation with fentanyl and midazolam was allowed. The dose administered was at the operator's decision.

#### **Definitions**

The imaging protocol was considered complete when selective catheterization of the coronary arteries and the left ventricle was achieved. Puncture time was defined as the time from local anesthesia to introducer insertion, and the total procedure time as the time from local anesthesia until the last catheter was removed.

#### **Outcomes**

The primary end point was the patient radiation dose during CA. Patient radiation exposure was measured as cumulative air kerma (kinetic energy released per unit of mass) in mGy and dose area product (DAP) in mGy·cm². The secondary end points were operating physician radiation exposure and major cardiovascular events at 30 days. Physician exposure (in  $\mu$ Sv) was assessed using an individual digital dosimeter (PM1621; Polimaster, Inc). The operating physician effective dose (ED) was determined according to the following formula: ED = (PD – BR) × CC, where PD is the procedure dose ( $\mu$ Sv), BR is the background radiation (procedure time [s] × 0.00004  $\mu$ Sv/s), and CC is the conversion coefficient (1.01).

#### Follow-Up

Patients were followed up at 24 hours for vascular complications, bleeding (using Global Utilization of Streptokinase and Tissue plasminogen activator in Occluded arteries [GUSTO] criteria), and stroke. They were then followed up at 30 days for major cardiovascular events.

#### **Sample Size and Statistical Considerations**

The EXPERT trial was designed as a noninferiority study, to show that TRA does not cause significantly more radiation exposure than TFA. A prior nonrandomized study by the same researchers<sup>16</sup> showed that diagnostic CA using TRA caused 39% more radiation exposure than CA using TFA (621.6 mGy vs 445.7 mGy). The EXPERT trial was based on the assumption that experienced interventional cardiologists could reduce this excess exposure; a sample size of 300 patients

was calculated to provide 80% power to detect any difference greater than 20% (relative margin) between groups.

Continuous variables were reported as the mean (SD) for normally distributed variables and as the mean (25th-75th percentile range) for those not normally distributed; these data were compared using the Student t test or the Mann-Whitney U test, as appropriate. Categorical variables were reported as the absolute number and percentage and were compared using the Pearson  $\chi^2$  test or the Fisher exact test. Predictors of higher radiation exposure were identified using multiple regression analysis. SPSS for Windows, version 16.0 software (IBM) was used for all analyses.  $P \leq .05$  was considered statistically significant.

All analyses followed the intention-to-treat principle, that is, if a patient's CA procedure was converted from TRA to TFA (or vice versa), the patient was included in their original group for analysis.

## **Masking and Randomization**

The operating physicians and patients could not be blinded to the intervention. However, the investigator who screened patients for the study and obtained informed consent was blinded to the treatment assignment. Numbered, sealed envelopes were used to randomly assign patients in a 1:1 ratio to the TRA and TFA groups. Operating physicians were informed about the assigned access method only when the patient was in the operating room, draped, and ready for the procedure.

## **Results**

Patients were enrolled between March 2013 and January 2014 (Fig. 1). Of the 300 patients, 1 was excluded (in the TFA group) because of a physician protocol violation (the minimum required imaging was not completed). There were 150 patients in the TRA group and 149 in the TFA group. As shown in Table I, there were no significant differences in baseline characteristics between groups.

## **Procedures**

As shown in Table II, the right radial and right femoral arteries were the most used access sites for CA. Coronary artery disease severity, left ventricular function, and the frequency of technical difficulties were compa-

**TABLE I. Patient Characteristics** 

	TRA $(n = 150)$	TFA $(n = 149)$	P value
Patient age, mean (SD), y	60.68 (11.6)	61.44 (11.4)	.56
Weight, mean (SD), kg	77.3 (15.3)	76.8 (13.8)	.78
Height, mean (SD), cm	170 (50)	166 (10)	.34
Body mass index, mean (SD)	27.7 (5.4)	27.7 (4.3)	.8
Male sex, No. (%)	78 (52)	82 (55)	.64
Current smoker, No. (%)	32 (21.3)	34 (22.8)	.86
Hypertension, No. (%)	118 (78.1)	119 (79.9)	.88
Diabetes, No. (%)	50 (33.3)	40 (26.8)	.27
Hyperlipidemia, No. (%)	67 (44.7)	54 (36.2)	.15
Severe valve heart disease, No. (%)	17 (11.3)	18 (12.1)	.84
Previous PCI, No. (%)	38 (25.3)	34 (22.8)	.70
Previous CABG, No. (%)	8 (5.3)	8 (5.4)	.99
Previous AMI, No. (%)	28 (18.7)	31 (20.8)	.74
Previous stroke, No. (%)	2 (1.3)	3 (1.8)	.99
Medications, No. (%)			
Aspirin	108 (72)	105 (70.5)	.86
Clopidogrel	28 (18.7)	38 (25.5)	.19
β-Blockers	102 (68)	95 (63.8)	.51
ACE inhibitors	73 (48.6)	61 (40.9)	.22
Diuretics	49 (32.7)	53 (35.6)	.68
Angiotensin receptor blockers	26 (17.3)	25 (16.8)	.99
Nitrates	40 (26.7)	36 (24.2)	.71
Calcium channel blockers	81 (13.3)	75 (14.8)	.84
Statins	81 (54)	65 (50.3)	.6
Oral antidiabetic agents	36 (24)	25 (16.8)	.16
Insulin	10 (6.7)	6 (4)	.44

ACE, angiotensin-converting enzyme; AMI, acute myocardial infarction; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; TFA, transfemoral approach; TRA, transradial approach.

rable between groups. The imaging protocol (coronary artery and left ventricle catheterization) was completed in 97.3% (146/150) of patients in the TRA group and 99.3% (148/149) of patients in the TFA group (P = .99). There were no differences in mean (SD) puncture time (TRA, 2.13 [1.8] vs TFA, 2.2 [4.9] min; P = .87), mean (SD) total procedure time (15.05 [4.8] vs 14.1 [4.3] min; P = .07), or mean (SD) fluoroscopy time (3.52 [2.18] vs 3.13 [2.43] min; P = .14). The number of projections used was also equivalent (TRA, 9.65 vs TFA, 9.68; P = .93). TRA required significantly less mean (SD) contrast volume (91.4 [21.2] mL vs 96.23 [23.7] mL; P = .05) and a smaller mean (SD) number of catheters (2.4 [0.3] vs 3.2 [0.6]; P < .001).

#### **Primary and Secondary End Points**

Table III summarizes the radiation exposure for patients (kerma and DAP) and physicians.

#### **Patients With Previous CABG**

In the TRA and TFA groups, 5.3% (8/150) and 5.4% (8/149) of patients had a history of CABG (P = .99). Procedural characteristics were similar between groups regarding the mean (SD) number of saphenous grafts per patient (2 [1] vs 2.5 [0.9]; P = .33), mean (SD) number of left internal mammary artery grafts per patient (1 vs 1, P = .99), mean (SD) number of angiographic views per procedure (12.6 [1.5] vs 13.1 [1.4]; P = .51), and mean (SD) fluoroscopy time (6.77 [3.75] vs 5.68

**TABLE II. Patient and Procedure Characteristics** 

	TRA $(n = 150)$	TFA $(n = 149)$	P value
Coronary stenosis >70%, No. (%)			.83
None	80 (53.3)	87 (58.4)	
1-vessel disease	38 (25.3)	34 (22.8)	
2-vessel disease	24 (16)	20 (13.4)	
3-vessel disease	8 (5.3)	8 (5.4)	
Ejection fraction, mean (SD), %	64.4 (12.7)	66.6 (13.4)	.14
Artery, No. (%)			.99
Right side	136 (90.6)	146 (97.9)	
Left side	14 (9.4)	3 (2.1)	
Catheter size, No. (%)			.70
5F	38 (25.3)	34 (22.8)	
6F	112 (74.7)	115 (77.2)	
Technical difficulties, No. (%)			<.001
None	107 (71.3)	140 (93.9)	
Spasm	28 (18.7)	0	
Tortuosity	15 (10)	9 (6.1)	
Crossover, No. (%)	3 (2)	0	.12

TRA, transradial approach; TFA, transfemoral approach.

**TABLE III. Patient and Physician Radiation Exposure** 

TRA $(n = 150)$	TFA (n = 149)	P value
616.51 (252)	585.57 (225)	.13
452	430	
602	553	
747	688	
35,496.5 (15,670.0)	38,313.4 (17,764.9)	.2
0.49 (0.3)	0.46 (0.29)	.32
	616.51 (252) 452 602 747 35,496.5 (15,670.0)	616.51 (252) 585.57 (225) 452 430 602 553 747 688 35,496.5 (15,670.0) 38,313.4 (17,764.9)

DAP, dose area product; kerma, kinetic energy released per unit of mass; mGy, milligray; µSv, microsieverts; TRA, transradial approach; TFA, transfemoral approach.

[2.43] min; P = .51). The TRA and TFA groups had comparable mean (SD) patient kerma values (760.1 [429] vs 872.7 [201] mGy; P = .51) and mean (SD) physician doses (1 [0.5] vs 0.8 [0.3]  $\mu$ Sv; P = .41). Likewise, the mean (SD) DAP did not differ significantly between groups (46,971.7 [29,259] vs 56,948.5 [17,552] mGy·cm²; P = .42).

#### **Patients With Severe Valvular Heart Disease**

Severe valvular heart disease was present in 11.3% (17/150) and 12.1% (18/149) of the TRA and TRA patients (P = .99). Mean (SD) patient radiation exposure

(557.2 [198] vs 613.2 [153] mGy; P = .35), mean (SD) operator exposure (0.56 [0.3] vs 0.64 [0.2]  $\mu$ Sv; P = .44), mean (SD) runs per procedure (9.94 [1.3] vs 9.67 [1.2]; P = .53), and mean (SD) fluoroscopy time (4.23 [2.51] vs 4.71 [2.9] min; P = .61) were similar between groups. However, mean (SD) DAP was significantly higher in the TFA group (32,737 [9,890] vs 41,428 [11,065] mGy·cm²; P = .02).

#### Follow-Up

There were no instances of in-hospital vascular complications, stroke, or bleeding (according to GUSTO criteria) in either group. At 30-day follow-up, 1 patient had experienced a stroke (not procedure related) in each group, and 2 patients in the TFA group (1.3%) experienced pseudoaneurysm. Almost all patients were completely asymptomatic: 99.3% in the TRA group and 98% in the TFA group (P = .24).

## **Predictors of Greater Radiation Exposure**

On examination of clinical characteristics that have traditionally been associated with TRA failure or greater radiation exposure, there were no significant predictors of higher radiation dose (Fig. 2).

## **Discussion**

The EXPERT trial, designed to compare TRA and TFA with radiation exposure as the primary end point, shows that the mean difference in radiation doses for patients (30.95 mGy) and physicians (0.03 mSv) did not differ between groups. These findings are important because they show that trained interventionalists can perform TRA and TFA with similar levels of occupational

radiation exposure. Therefore, concerns about higher radiation doses and the stochastic effect, increasing the risk of cancer induction, can be minimized with extensive physician training.

The greater radiation exposure that previous studies show for TRA11,16 may be the result of bias from an important confounding factor: unknown details of image capture. Imaging technique is an important determinant of radiation exposure during x-ray-based procedures.<sup>17</sup> Steeply angled x-ray beams, higher magnification modes, use of filters or collimators, longer fluoroscopy times, and higher frame rates are predictors of higher levels of radiation. However, previous studies did not control for these factors. The EXPERT trial was designed to minimize these possible sources of bias by using roughly the same total number of projections per group, a standardized imaging protocol, prespecified flat detector angulations, and adequate protective equipment; these precautions ensure that the imaging acquisition process does not affect the amount of x-ray radiation during CA. Therefore, it seems safe to assume that the difference in radiation exposure is related to the technique and not to confounding factors.

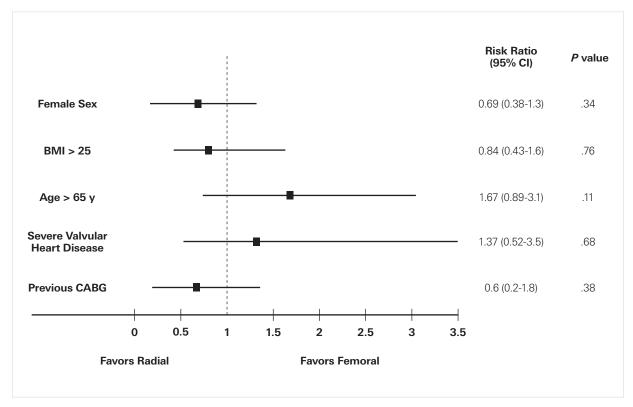


Fig. 2 Factors potentially associated with radiation exposure.

BMI, body mass index; CABG, coronary artery bypass graft.

Another possible source of bias in previous studies is operator expertise in TRA. The operator's location on the learning curve plays an important role in TRA efficacy. The RIVAL trial<sup>13</sup> showed that the efficacy of radial access might be linked to operator expertise and volume. A substudy by the same researchers<sup>18</sup> also reported that high-volume centers have the lowest radiation doses, regardless of which access site they use. The effects of operator expertise are controlled for in the EXPERT trial because all operators had the same level of expertise (SCAI level III competency).14 Puncture and fluoroscopy times were just few seconds longer in the TRA group than in the TFA group. In addition, the rates of successful CA and TRA crossover do not differ between groups. Thus, in concordance with other studies, 19,20 this trial shows that TRA is feasible and incurs a radiation dose and other outcomes similar to those of TFA when performed by well-trained physicians.

Patient selection might also affect TRA efficacy; most previous trials exclude patients with severe valvular heart disease and previous CABG. In the EXPERT trial, these 2 characteristics are not exclusion criteria: 5% of patients have severe valve disease, and 12% have a history of CABG, making this patient cohort more reflective of the real-world patient population. In a dedicated trial to evaluate the utility of TRA for patients with previous CABG, Michael et al<sup>21</sup> showed that CA is feasible but associated with greater radiation exposure for patients and operators. Recently, Manly et al<sup>22</sup> published data from CathPCI Registry (part of the American College of Cardiology's National Cardiovascular Data Registry) showing that the use of TRA in the United States has been increasing since 2009. Although TRA is associated with certain benefits, it seems that only physicians experienced in using TRA for patients who do not have a history of CABG are using it for patients with previous CABG.<sup>22</sup> Thus, the literature demonstrates that experienced operators can safely perform TRA for routine CA regardless of patient complexity.

In the EXPERT trial, the most commonly used access site is the right radial artery. Compared with right-sided TRA, left-sided TRA is associated with easier procedures<sup>23</sup> because it more closely mimics TFA in terms of catheter manipulation. In addition, subclavian artery tortuosity is less frequent on the left side than on the right. Several studies have evaluated whether right or left radial access is preferable. For patients, both sides are equivalent. However, results conflict regarding radiation exposure for physicians.<sup>20,24-26</sup> Recently, the

Randomized Evaluation of Vascular Entry Site and Radiation Exposure (REVERE) trial<sup>19</sup> compared the CA radiation exposure associated with femoral, left radial, and right radial approaches, finding that radiation dose does not differ by entry site. However, operator exposure is less with the femoral approach. Left radial access is associated with a larger radiation dose than is right radial access, but the difference is only 0.003 millisieverts by dosimetry measurement. The EXPERT study confirms that the right and left radial approaches are both feasible and provide radiation exposure equivalent to that of femoral access. Thus, operator preference should dictate which side to use.<sup>27</sup>

From the physician perspective, the EXPERT trial shows that TRA is associated with slightly (6%)—but not significantly—more radiation exposure than is TFA. Perhaps, operators performing TRA might reduce their radiation dose by using disposable radiation-blocking drapes, <sup>28</sup> lead shields draped over the patient, <sup>29</sup> and a low fluoroscopy rate. <sup>30</sup> Although it was not tested in the present trial, previous studies have shown that these simple but costly strategies are associated with a meaningful reduction in x-ray exposure. Intensive TRA training to maximize the use of x-ray protection measures surely will reduce occupational radiation exposure for physicians. <sup>31</sup>

This study has 3 main limitations. First, the operators have substantial experience in TRA, so the present results may not be easily and widely replicable in routine practice. However, these findings may encourage other physicians to overcome the TRA learning curve and achieve similar results. Second, although the relative margin in radiation doses is wide (20%), the results show that TRA does not expose patients and operators to higher radiation doses. Third, the recently introduced distal radial approach (ie, the "snuff box" technique) was not tested in this trial, and its results cannot be extrapolated to that technique.

## **Conclusion**

The results of the EXPERT trial suggest that, in terms of radiation exposure, TRA for elective CA is noninferior to TFA when performed by experienced operators. Continuous training is required for interventional cardiologists to overcome the learning curve associated with TRA and minimize radiation exposure.

## **Acknowledgments**

Stephen N. Palmer, PhD, ELS, contributed to the editing of the manuscript.

Published: 22 March 2023

**Correction:** The online article and PDF were corrected on 21 April 2023. Hazard ratio (HR) was changed to risk ratio (RR) throughout the text and in Figure 2.

**Conflict of Interest Disclosures:** None of the authors has any conflicts of interest.

**Funding/Support:** No funding support was provided for this study. It is registered under ClinicalTrials.gov identifier NCT01794325.

**Academic Information:** This article describes part of Dr Cardoso's PhD thesis research at the Graduate Program in Health Sciences (Cardiology - PPG), University Foundation of Cardiology, Porto Alegre, Rio Grande do Sul, Brazil.

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