Operator Radiation Exposure During Percutaneous Coronary Procedures Through the Left or Right Radial Approach

The TALENT Dosimetric Substudy

Alessandro Sciahbasi, MD; Enrico Romagnoli, MD, PhD; Carlo Trani, MD; Francesco Burzotta, MD, PhD; Alessandro Sarandrea, Ph Eng; Francesco Summaria, MD; Roberto Patrizi, MD; Sunil Rao, MD; Ernesto Lioy, MD

Background—Transradial percutaneous coronary procedures may be effectively performed through the right radial approach (RRA) or the left radial approach (LRA), but data on radiation dose absorbed by operators comparing the two approaches are lacking. The aim of the present study was to evaluate radiation dose absorbed by operators during coronary procedures through the RRA and LRA.

Methods and Results—Three operators were equipped with 5 different dosimeters (left wrist, shoulder, thorax outside the lead apron, thorax under the lead apron, and thyroid) during RRA or LRA for coronary procedures. Each month, the dosimeters were analyzed to determine the radiation dose absorbed. From February to December 2009, 390 patients were randomly assigned to the RRA (185 patients; age, 66±11 years) or the LRA (185 patients; age, 66±11 years). There were no significant differences in fluoroscopy time (for RRA, 369 seconds; interquartile range, 134 to 857 seconds; for LRA, 362 seconds; interquartile range, 142 to 885 seconds; P=0.58) between the 2 groups. There were no significant differences in monthly radiation dose at the thorax (0.85±0.46 mSv for RRA and 1.12±0.78 mSv for LRA, P=0.33), at the thyroid (0.36±0.2 mSv for RRA and 0.34±0.3 mSv for LRA, P=0.87), and at the shoulder (0.73±0.44 mSv for RRA and 0.94±0.42 mSv for LRA, P=0.27). The dose at the wrist was significantly higher for the RRA (2.44±1.12 mSv) compared with the LRA (1.00±0.8 mSv, P=0.002). In both radial approaches, the thoracic radiation dose under the lead apron was undetectable.

Conclusions—Compared with RRA, LRA for coronary procedures is associated with similar radiation dose for operators at the body, shoulder, or thyroid level, with a possible significant advantage at the wrist. The cumulative radiation dose for both approaches is well under the annual dose-equivalent limit.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00282646.

Key Words: transradial approach ■ left radial ■ right radial ■ radiation dose
subgroup analysis of the TALENT Study to evaluate the operator and patient radiation dose during percutaneous coronary procedures performed through the LRA or the RRA.

Methods

The TALENT study (Transradial Approach [Left versus right] and procedural Times during percutaneous coronary procedures) is a randomized, dual-center study aimed to evaluate safety and efficacy of the LRA compared with the RRA for percutaneous coronary diagnostic and interventional procedures. The design and results of the study have been previously described in detail. In brief, from January 2009 to December 2009, 1540 patients were randomly assigned to RRA (770 patients) or LRA (770 patients) for percutaneous coronary procedures. Transradial procedures were performed by 10 expert operators (seniors) and 6 operators in training (fellows).

During this study, from February 2009 to December 2009, 3 expert operators (>200 transradial procedures per year) were equipped with 5 different dosimeters to evaluate the operator radiation dose. All procedures performed by these operators were included in this substudy.

Patient allocation to one of the two approaches was made by means of a concealed computer-generated random sequence. The randomization list was managed by the nursing staff, who informed the interventional cardiologist of the assigned approach just before the procedure.

Exclusion criteria were previous coronary artery bypass, hemodynamic instability, ST-elevation–acute myocardial infarction, need of catheters >6F, ischemic Allen test, simultaneous right heart catheterization, hemodialysis patients with an arteriovenous fistula, and age <18 years.

The study was approved by institutional ethics committee, and written informed consent was obtained from the participants.

Cardiac Catheterization and Percutaneous Coronary Intervention

A 5F or 6F artery sheath was used in all cases. The Allen test was performed before the procedure, and patients with ischemic results were excluded. The radial artery approach was performed using a hydrophilic guide wire and hydrophilic sheath (Radifocus, Introducer II, Terumo Corporation, Tokyo, Japan). After sheath insertion, 5000 U of unfractioned heparin was injected directly into the radial artery through the sheath. Additional units of unfractioned heparin were given before the interventional procedure, according to the activated clotting time results. A spasmolytic cocktail to reduce radial spasm was not routinely used, and in the case of radial spasm, direct arterial injection of nitrates or verapamil was allowed.

In both approaches, the arm was positioned along the patient’s leg or, if possible, in the case of LRA, over the left leg (Figure 1).

Selective catheterization of the right and left coronary arteries was carried out using Judkins curve catheters (right and left). Different curve catheters were used in the case of inability of the default catheters to engage the coronary ostia.

Contrast injection was performed with the use of an automatic power injection device that allows for online control of contrast injection rate and volume.

All the procedures were performed in the same angiographic room, equipped with a flat-panel angiographic detector (Allura, XPER FD 10, Philips, Eindhoven, The Netherlands) installed in July 2008. The angiographic system is equipped with a 3-field, 25-cm image intensifier (25 cm/20 cm/15 cm), and operators used the 25-cm intensifier during catheter manipulation and the 20-cm intensifier during cine recording. Dose-rate options are also available (high, normal, and low fluoroscopy), and the system was automatically set on the lowest fluoroscopy option. The number of frames per second for fluor and cine was automatically set to 15 frames per second for all operators. The dose-area product (DAP) was directly measured by the collimator of the angiographic system.

For all diagnostic procedures, 4 different projections (left cranial, right cranial, left caudal, and right caudal) were performed. Further diagnostic projections were allowed in the case of insufficient angiographic documentation.

Radiation Protection

Operator radioprotection was ensured through the use of a lead apron (2 layers of 0.25-mm lead, equating to 0.5 mm in the front of the operator), a thyroid lead collar, low leaded flaps, an upper mobile leaded glass suspended from the ceiling, and leaded glasses (0.5-mm leaded equivalent for each) in all procedures.

Radiation Measurement

Operator radiation exposure was assessed using 5 pair dosimeters dedicated for the LRA (yellow dosimeter) or the RRA (blue dosimeter). According to the randomization, each operator located the 5 dosimeters at the left wrist, left shoulder, in the middle thorax outside the lead apron, in the middle thorax under the lead apron, and at the thyroid level outside the lead collar. Each month, the 5 pair dosimeters were sent to TECNORAD s.r.l. (Verona, Italy) to measure the radiation dose and were substituted with new dosimeters. Monthly effective doses were expressed in milliSv. The radiation dose adsorbed by operators was measured using lithium fluoride thermoluminescent dosimeters, with a range of linearity from 1 μGy to 10 Gy.

Effective doses delivered to patients were expressed as DAP and expressed in Gy cm². For those patients who had a percutaneous coronary intervention after the diagnostic procedure, the measurement of fluoroscopy time, DAP, and contrast amount were reset and restarted after the end of the diagnostic procedure.

In 6 patients not included in the cohort of the study and who had a simultaneous RRA and LRA for the treatment of a coronary
chronic total occlusion, we also performed a snapshot recording of the actual radiation dose during fluoroscopy at the left wrist level. We used an ionization chamber (RAM ION X Meter) with a radiation range of 0.1 to 1 μSv/ h. A snapshot radiation measurement during catheter manipulation in the anteroposterior projection and the radiation dose per hour (expressed as μSv/ h) measured during 5 seconds of fluoroscopy were determined.

End Point
The primary end point of the study was the radiation dose absorbed by operators as detected by the 5 dedicated dosimeters, comparing the LRA and the RRA.

Statistical Analysis
Continuous variables for each of the 2 groups are reported as means and standard deviations for variables normally distributed and as medians with interquartile range for those not normally distributed and were compared using the Student’s t test or Mann-Whitney U test as appropriate. Multiple group data were compared by ANOVA, using the unpaired t test for multiple comparisons with Bonferroni adjustment. Radiation doses of different dosimeters in the same patients were compared using 1-way ANOVA, and, in the case of statistical significance, post hoc analysis was performed using the Scheffé test. Categorical variables are indicated as the absolute number and percentage and were compared using the Fisher exact test. Results are expressed as mean ± SD. RRA indicates right radial approach; LRA, left radial approach.

Table 1. Characteristics of Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RRA (n=185)</th>
<th>LRA (n=185)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>66±11</td>
<td>66±11</td>
<td>0.90</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>128 (69)</td>
<td>125 (68)</td>
<td>0.73</td>
</tr>
<tr>
<td>Height, cm</td>
<td>168±8</td>
<td>167±10</td>
<td>0.38</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>78±15</td>
<td>78±14</td>
<td>0.75</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>28±5</td>
<td>28±4</td>
<td>0.26</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>60 (32)</td>
<td>63 (34)</td>
<td>0.74</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>124 (72)</td>
<td>112 (61)</td>
<td>0.19</td>
</tr>
<tr>
<td>Creatinine, mg/dL</td>
<td>1.1±1</td>
<td>1±0.9</td>
<td>0.45</td>
</tr>
<tr>
<td>Glomerular filtration rate, mL/min</td>
<td>91±38</td>
<td>95±34</td>
<td>0.28</td>
</tr>
<tr>
<td>Hemoglobin, g/dL</td>
<td>13.4±1.7</td>
<td>13.2±1.9</td>
<td>0.40</td>
</tr>
<tr>
<td>Acute coronary syndromes, n (%)</td>
<td>104 (56)</td>
<td>105 (57)</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Results
Of the 390 patients randomly assigned in the study (185 RRA and 185 LRA), 350 patients (173 RRA and 177 LRA) underwent a diagnostic coronary angiography, and in 190 patients (95 each for LRA and RRA), a percutaneous coronary intervention was performed after the diagnostic angiography or as a stand-alone procedure (Figure 2). The baseline characteristics of the patients are summarized in Table 1 and were similar between the 2 groups. There were no significant differences in the vessels treated during percutaneous coronary intervention between the RRA (31 left anterior descending, 29 circumflex, and 35 right coronary artery) and the LRA (33 left anterior descending, 31 circumflex, and 31 right coronary artery). Most of the procedures were single-vessel percutaneous coronary intervention, with only 3 cases of multivessel percutaneous coronary intervention for either the RRA or the LRA. The number of bifurcations treated was low and slightly higher in the RRA (17 cases) compared with the LRA (11 cases, P = 0.30). The height, weight, and body mass index of the 3 operators involved in the study were 181±5 cm, 77±6 kg, and 23±1 kg/m².

Radiation Dose
There were no significant differences between the 2 groups in fluoroscopy time, DAP fluoroscopy, DAP fluorography, and contrast amount, either during diagnostic coronary procedures or during percutaneous coronary intervention (Table 2). Among the different dosimeters, those positioned at the wrist received the highest radiation dose (Figure 3, P<0.0001), but this difference was significant only in the RRA group (Figure 3). Comparing the 2 radial approaches, the dosimetric analysis did not show significant differences in the monthly adsorbed dose for thorax over the lead apron (0.85±0.46 mSv for RRA and 1.12±0.78 mSv for LRA, P = 0.33), for the thyroid (0.36±0.2 mSv for RRA and 0.34±0.3 mSv for LRA, P = 0.87), and for the shoulder (0.73±0.44 mSv for RRA and 0.94±0.42 mSv for LRA, P = 0.27). Monthly radiation dose at the wrist was significantly higher for the RRA (2.44±1.12 mSv) compared with the LRA (1.0±0.8 mSv, P = 0.002). In both radial approaches, the thoracic radiation dose under the lead apron was undetectable.

The cumulative annual dose for the RRA (3.99 mSv for the thyroid, 26.85 mSv for the wrist, 8 mSv for the shoulder, and 9.35 mSv for the thorax) and for the LRA (3.79 mSv for the thyroid, 10.97 mSv for the wrist, 10.33 mSv for the shoulder, and 12.33 mSv for the thorax) were low and very far from the annual dose equivalent limit allowed. Moreover, the extrapolated procedural dose for the RRA (0.02 mSv for the thyroid, 0.15 mSv for the wrist, 0.04 mSv for the shoulder, and 0.05 mSv for the thorax) and for the LRA (0.02 mSv for the thyroid, 0.06 mSv for the wrist, 0.06 mSv for the shoulder, and 0.07 mSv for the thorax) were also low.

In the RRA and in the LRA, the radiation dose for all dosimeters was highly correlated with fluoroscopy time and total (fluoroscopy plus fluorography) DAP (Table 3).
Radiation Dose During Combined Left and Right Radial Cannulation

In the 6 patients who underwent a combined simultaneous right and left radial cannulation for the treatment of a coronary chronic total occlusion, the snapshot evaluation of the radiation dose at the wrist confirmed significantly higher exposure during RRA (1.07+/−0.7 μSv/h(1/1000)) compared with LRA (0.22+/−0.1 μSv/h, P=0.02). Moreover, during a 5-second fluoroscopy, the radiation dose per hour was also significantly higher during RRA (534.5+/−387 μSv/h) compared with LRA (190.8+/−71 μSv/h, P=0.05).

Discussion

The use of the radial approach for percutaneous coronary procedures is progressively increasing, and many efforts have been directed at facilitating this approach. We recently showed that the LRA may have some advantage over the RRA, particularly in physicians in training and in older patients. However, there are some concerns regarding a possible increase in operator radiation exposure linked to the closer position to the patient and reaching directly over the radiation source underneath the cath laboratory table. In the present study, we did not observe significant differences in operator radiation dose between the two approaches for most of the body (thorax, thyroid, or shoulder); conversely the radiation dose to the left hand during the RRA was significantly higher compared with the LRA. This difference is independent of fluoroscopy time or the DAP, which were not significantly different between the two approaches. Thus, these data provide confirmation that concerns over the LRA with respect to radiation exposure are unfounded in a population of normal-weight patients.

The reason for the dosimetric advantage of the LRA at the wrist may be linked to different reasons, such as the position taken by the operator during LRA and RRA or the different positioning of the upper mobile leaded glass suspended from the ceiling (over the right arm in the RRA and over the patient’s body in the LRA), which might have better shielded the operator’s wrist during the LRA compared with the RRA. Because some variables such as body mass index, the treatment of complex lesions, and the different angulation of the X-ray tube may have biased the radiation dose, we also tested our hypothesis in 6 cases of simultaneous left and right radial cannulation during fluoroscopy in the anteroposterior position of the X-ray tube. In these cases, a snapshot evaluation of the radiation dose to the operator’s left arm

Table 2. Procedural Data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cumulative</th>
<th>Coronary Angiography</th>
<th>PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RRA (n=185)</td>
<td>LRA (n=185)</td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy, s</td>
<td>369 (134–857)</td>
<td>362 (142–885)</td>
<td>0.58</td>
</tr>
<tr>
<td>DAP fluoro, Gycm²</td>
<td>21.5 (7–64)</td>
<td>22.9 (8–67)</td>
<td>0.56</td>
</tr>
<tr>
<td>DAP cine, Gycm²</td>
<td>32.9 (21–62)</td>
<td>37.2 (22–65)</td>
<td>0.54</td>
</tr>
<tr>
<td>Total DAP, Gycm²</td>
<td>57.4 (30–126)</td>
<td>60.4 (30–137)</td>
<td>0.57</td>
</tr>
<tr>
<td>Contrast dose,* mL</td>
<td>140±104</td>
<td>150±109</td>
<td>0.37</td>
</tr>
</tbody>
</table>

Results are expressed as median with interquartile range. RRA indicates right radial approach; LRA, left radial approach; PCI, percutaneous coronary intervention.

*Mean±SD.

Figure 3. Radiation dose detected by the 4 dosimeters over the lead apron. Radiation dose at the wrist was significantly higher compared with the rest of the body, but this difference was significant only in the right radial approach group.
showed significantly higher doses for the RRA compared with the LRA when movable shields were properly positioned. However, the possible advantage of the LRA at the wrist should be confirmed by using different operator and shield positioning. Moreover, we must consider that the radiation doses adsorbed at the wrist (a nonsensitive organ) are well under the annual dose-equivalent limit.

The radiation issue is important for operators because of the long-term stochastic risk of cancer induction, but it is often underevaluated. Even if the stochastic risk is an all-or-none phenomenon for any individual cell, the greater the radiation exposure, the more cells are injured. Moreover, noncancerous effects are possible, such as cataract formation in the eye, and the probability increases with increasing doses. Consequently, even the small, nonsignificant, higher dose detected for the LRA at the thorax and the shoulder and for the RRA at the wrist may have a clinical impact in the long term, and operators should apply all efforts to reduce the radiation dose. However, it is reassuring that the radiation dose beneath the lead apron, with appropriate radioprotection using the glass screen and lead flaps, was undetectable.

Consistent with previous studies, and in our experience, the operator exposure dose is higher at the operator’s left wrist compared with the rest of the body, and this difference is particularly significant during the RRA. Therefore, efforts should be made to reduce the radiation dose to the left hand, particularly when performing the RRA. Recently, different techniques and devices have been proposed to reduce the operator radiation exposure, with varying results. The efficacy of these strategies has yet to be confirmed in adequately powered studies.

According to our results, showing no significant differences between the two approaches, the choice of the right or the left approach should be left to operator discretion considering the personal preference and the specific patient who must be treated.

The major disadvantage of the LRA is the operator discomfort caused by the position taken during the procedure, that is, the need to reach with the left arm and bend over the patient increases the work load for the operator’s back. In the case of very obese patients, the LRA may be difficult. Consequently, in the case of very obese patients and particularly in the case of short operators, the LRA should be avoided.

A limitation of our study is the monthly determination of the radiation dose rather than the evaluation per single procedure. Moreover, all operators used the same dosimeters, and consequently an analysis per operator or per procedure is not feasible. We cannot exclude that differences between operators may have affected the results: Indeed, even if all operators worked in the same angiographic room with the same procedural standard, there may be significant interoperator variations of the treatment dose caused by factors such as tube angulation or operator position. An important limitation of our study is the patient size: According to the weight of our population, the results can be applicable only to normal-weight patients. We cannot exclude that in overweight patients, as those observed in different countries, the dosimetric measurement could give different results. Another limitation is the lack of dedicated dosimeters for the legs, which are the closest part of the body to the radiation source.

Finally, our results cannot be generalized to other cardiac catheterization laboratories because there may be major differences in operators’ training, protection devices, cath laboratory setup, and technical equipment.

## Conclusions

In normal-weight patients, compared with the RRA, the LRA for percutaneous coronary diagnostic and interventional procedures showed a similar radiation dose adsorbed by operators at the thorax, thyroid, or shoulder. The possible advantage of the LRA at the wrist should be confirmed by using different operator and shield positioning.

## Disclosures

Dr Rao is a consultant for Sanofi-Aventis, BMS, Astra Zeneca, Daiichi-Sankyo Lilly, and Terumo and received research funding from Ikaria, Novartis, and Cordis.

## References


**CLINICAL PERSPECTIVE**

There is no consensus opinion for preferred radial artery access site with respect to operator radiation exposure when performing coronary procedures. The main finding of this prospective, randomized, dual-center study is that the left and right radial approaches for coronary procedures showed similar radiation dose absorbed by operators at the body, shoulder, and thyroid levels; there was a suggestion of an advantage for the left approach in terms of radiation dose absorbed at wrist. Because there are some concerns for the left transradial approach in terms of radiation dose absorbed by operators, these data provide evidence that these concerns are unfounded when operators are of average height and weight and procedures are performed in a population of normal-weight patients. Moreover, the cumulative radiation dose absorbed by operators for both right and left radial artery approaches is low and well under the annual dose-equivalent limit.
Operator Radiation Exposure During Percutaneous Coronary Procedures Through the Left or Right Radial Approach: The TALENT Dosimetric Substudy
Alessandro Sciahbasi, Enrico Romagnoli, Carlo Trani, Francesco Burzotta, Alessandro Sarandrea, Francesco Summaria, Roberto Patrizi, Sunil Rao and Ernesto Lioy

Circ Cardiovasc Interv. published online May 17, 2011;
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2011 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7640. Online ISSN: 1941-7632

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circinterventions.ahajournals.org/content/early/2011/05/17/CIRCINTERVENTIONS.111.961185

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Cardiovascular Interventions can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Cardiovascular Interventions is online at:
http://circinterventions.ahajournals.org//subscriptions/