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Determinants of radiation dose during right transradial access: Insights from the RAD-Matrix study

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Abbreviated title: Determinants of radial access radiation dose

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Conflicts of Interest

Dr. Cortese reports personal fees from The Medicines Company, during the conduct of the study;Dr. Valgimigli reports grants from Terumo and grants from The Medicines Company, during the conduct of the study. The other authors report nothing to disclose related to the content herein.

Structured Abstract

Background: The RAD-MATRIX trial reported a largeoperator radiation exposure variability in right radial percutaneous coronary procedures. The reasons of these differences are not well understood. Our aim was toappraisethe determinants of operator radiation exposure during coronary right transradial procedures.

Methods: Patient arrangement during trans-radial intervention was investigated across operators involved in the RAD-MATRIX trial. Operator radiation exposure was analyzed according to the position of the patient right arm (close or far from the body) and in relation to the size of the upper leaded glass.

Results: Amongst the 14 operators who agreed to participate, there was a greater than 10-fold difference in radiation dose at thorax level (from 21.5 µSv to 267 µSv) that persisted after normalization by DAP (from 0.35 µSv/Gy*cm^2 to 3.5 µSv/Gy*cm^2). Among the operators who positioned the instrumented right arm far from the body (110.4 µSv, Interquartile range 71.5-146.5 µSv) thorax dose was greater than those who placed the instrumented arm close to the right leg (46.1 µSv, 31.3-56.8 µSv, p=0.02). This difference persisted after normalization by DAP (p=0.028). The use of a smaller full glass shield was also associated with a higher radiation exposure compared to a larger composite shield (147.5 µSv, and 60 µSv, respectively, p= 0.016).

Conclusions: In thecontext of the biggest radiation study conducted in patients undergoing trans-radial catheterization, the instrumented right arm arrangement close to the leg and greater upper leaded shield dimensions were associated with a lower operator radiation exposure. Our findings emphasize the importance of implementing simple preventive measures to mitigate the extra risks of radiation exposure with right radial as compared with femoral access.

Key Words: Radiation dose –Radial access –Femoral access –Acute coronary syndromes –PCI

Introduction

The use of radial, instead of femoral, access for coronary angiography and percutaneous coronary intervention (PCI) has recently gained worldwide acceptance due to lower risks of bleeding, vascular complications and patients discomfort (1-3). The MATRIX trial (1)showed a greater survival in patients with acute coronary syndrome undergoing invasive management treated by transradial rather than transfemoral approach. This observation, in conjunction with prior evidence, has led the European clinical practice guidelines to endorse the use of radial access in patients with acute coronary syndromes undergoing invasive management with a class I recommendation(4, 5).

However, the right radial access site, which is by far the most frequently used transradial route worldwide, is associated to higher radiation exposure, especially for operators, as compared to the femoral approach (6-9). A possible explanation of the higher dose in radial access is due to the operators difficulty in adequately shield themselves from the scatter radiation coming from the patient. The use of adjunctive protective drapes placed on the patient have been proved to be effective methods to significantly reduce this scatter radiation coming from the patientreducing the operator radiation exposure in transradial procedures(10-11).

A significant variability in operator radiation dose has been documented among operators performing transradial procedures in the largest study evaluating operator radiation exposure during percutaneous coronary interventions (12). The reasons of this heterogeneity are likely multifactorial (position of the operator, use of adequate shield, positioning of the shield, radiation dose utilized, etc.) but not completely understood.

At variance with the transfemoral approach, the arrangement for patients undergoing right radial access lacks standardization. In particular some operators position the patient right arm along to the patient right leg, whereas other operators prefer to undertake catheterization while the right arm lies abducted from the patient leg. These two different arrangements reflect a different positioning of the operator during the procedure and differential use of the upper mobile leaded glass. No studies,to date, evaluated therole of the different patient arrangements in terms of operator radiation dose.

The aim of this analysis of the RAD-MATRIX study, is to appraise the determinants of operator radiation exposure during right transradial approach.

Methods

Study design and population

The designs of the MATRIX trial and of the radiation (RAD-MATRIX) substudy have been previously reported (13,14). In brief, all patients with an ACS with or without ST-segment elevation myocardial infarction were randomly allocated to radial or femoral access.

Operators participating in the radiation sub-study were asked to follow central randomization in regards to radial or femoral access for the primary endpoint comparison (operator radiation exposure at thorax), and for the patient radiation exposure comparison. A further randomization was performed in patients centrally allocated to radial access based on the patient identification (ID) number with odd ID numbers assigned to right radial and even ID numbers to left radial access. In the present analysis we considered only the right radial access procedures.

Procedures

Access site management during and after the diagnostic or therapeutic procedure was left to the discretion of the treating physician. Patient and operator positioning during trans-radial catheterization was according to institutional standards.

In all procedures, radioprotection was ensured using a lead apron, a thyroid lead collar, lower body X-ray curtain fixed on the angiographic table and an upper mobile leaded glass suspended from the ceiling.

Radiation Measurement

Each operator was equipped with dedicated lithium fluoride thermo-luminescent dosimeters with a range of linearity from 1 µGy to 10 Gy placed at left wrist, at mid thorax level, in the breast pocket outside the lead apron and at head level (in the middle front to measure the eye dose). At the end of the study, all the dosimeters were collected for central reading at TECNORAD co. (Verona, Italy) and represent cumulative exposure during all procedures performed by the operator that were divided by the number of procedures performed in order to obtain the operator mean radiation dose. The results were expressed as Equivalent doses in microSievert after correction for the radiation weighting factor (for X rays this factor is 1).

Procedural dose was estimated using the Dose Area Product (DAP) expressed in Gy*cm2. The DAP is the product of the absorbed dose to air and the cross-sectional area of the X-ray field for all segments of an interventional radiology procedure. This parameter was measured using specially designed ionization chambers mounted at the collimator system and calculated by the software present in each angiographic system.

There were no significant differences in operator positioning in relation to the radiation source.

Patient set-up and upper mobile leaded glass

Description of patient set-up was performed asking to the operators involved in the study to take representative picturesillustrating the positions of patient's right arm as well of the operators during trans-radial catheterization. After centralised analysis of each operator's representative pictures, two different arrangements of the patient right arm were identified: straight close to the right leg (Group A) or far from the body (Group B, Figure 1).

In addition two different upper mobile leaded shields were identified across participating centers: a full glass shield (60 cm of height) or a combined glass and curtain leaded shield (35 cm each for a total height of 70 cm, Figure 2).

Statistical analysis

Continuous variables are reported as mean and standard deviation and compared using T-Test. Categorical variables are indicated as the absolute number and percentage and were compared by Pearson's chi-square test or, if the number expected of patients was less than five, with the Fisher's exact test.

Operator radiation doseand fluoroscopy time were presented as median with interquartile range and compared by Mann Whitney U test. The operator radiation dose was also normalized by DAP to exclude a possible bias due to the complexity of the procedure or to the anthropometric characteristics of the patients.

The analyses were performed using SPSS 21.0 software (SPSS, Chicago, Illinois, USA).

Endpoints

The primary end-point of the study was operator radiation exposure at thorax level during right radial procedures comparing the two arrangements of patient right arm (Group A vs B) as previously described. Secondary end-point was operator radiation exposure comparing the two identified upper mobile shields across participating institutions.

Extramural funding

The MATRIX program is conducted with support from The Medicines Company and Terumo.

The RAD MATRIX sub-study did not receive additional funding and has been co-supported by Alessandro Sciahbasi, the sub-study principal investigator.

The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

Results

From a total of 18 operators involved in the study, 1 operator did not qualify due to refusal to perform right transradial procedures and 3 operators declined participation due to impossibilityto provide representatives pictures while the recruitment in the RAD-MATRIX trial took place.

Overall, the 14 included operators performed 139 procedures (10 ± 7 procedures per operator) through the right transradial access. Among these operators, there was a more than 12-fold variability in the procedural radiation exposure at thorax level (Range: 21.5 µSv to 267 µSv)and a roughly five-fold difference for DAP (Range: 37 Gy*cm^2 to 167 Gy*cm^2). After normalization of radiation dose by DAP, a 10-fold inter-operator variability still persisted ranging from 0.35 µSv/Gy*cm^2 to 3.5 µSv/Gy*cm^2.

Patient preparation and operator dose

Six operators arranged the patient right arm along the patient right leg (Group A) whereas 8 operators were used to install the patient right arm far from the body (Group B). The two groups did not differ significantly for clinical and procedural characteristics except for a higher STEMI rate in group A(Table I).

In group A, the operator procedural radiation dose at thorax level was significantly lower compared to Group B (46.1 µSv, IQR 31.3-56.8 µSv and 110.4 µSv, IQR 71.5-146.5 µSv, respectively, p= 0.02). After normalization by DAP the difference still persisted (0.55µSv/Gy*cm^2, IQR 0.49-0.62 µSv/Gy*cm^2, in Group A and 0.91µSv/Gy*cm^2, IQR 0.73-1.24 µSv/Gy*cm^2, in Group B, p= 0.028). Similar results were observed at head level whereas at left wrist despite numerically higher level in Group B, the difference was not statistically significant (Table II).

Dimension of the upper mobile leaded glass

The three operators who used the full glass shield had a significantly higher radiation dose compared to the 11 operators that used the combined (glass and curtain) shield (147.5 µSv, IQR 135.5-207.3 µSv and 60 µSv, IQR 44.1-73.8 µSv respectively, p= 0.016). After normalization by DAP a trend was still noted towards higher radiation dose in operators using full glass shield (1.05 µSv/Gy*cm^2, IQR 0.9-2.28 µSv/Gy*cm^2, vs0.71 µSv/Gy*cm^2, IQR 0.48-0.76 µSv/Gy*cm^2, p= 0.07).

Discussion

At variance with transfemoral access, transradial procedures are associated with a large variability across centres in term of patient preparation and radio-protective measures used during catheterization.

In the setting of the largest study evaluating the radiation exposure in patients and operators during percutaneous coronary interventions with radial or femoral access we previously reported that radial, especially when access in the right arm, as compared with femoral access is associated with greater operator and patient radiation exposure. The key and novel information provided by this study is that a different patient set-up for percutaneous coronary procedures through the right radial access hasa remarkably large impact on the operator radiation exposure. The lower operator exposure was observed when the instrumented right arm was positioned along the right leg as compared to operators instrumenting the right radial arm while abducted from the thorax.

Our findings are independent from the anthropometric patient characteristics or procedural radiation dose since these observations have been confirmed when the operator radiation dose was normalized by DAP.

The possible explanation of this difference in radiation dose between the two set-upsis based on the different use of the upper mobile shield in the two arrangements. Indeed in case of external position of the patient arm the operator generally place the upper mobile shield morelaterally, in a position that could be less effective(Figure 3, Panel A). Differently, when the arm is placed along and very close to the right leg the operator has no difficulty to place the upper shield more medially increasing its efficacy as radiation shield (Figure 3, Panel B). The results observed at head and wrist level confirmed our interpretation: previous studies showed that the upper mobile shield is very effective to reduce thorax and head radiation whereas the efficacy at left wrist level is weak (15-16).

According to our findings a simple measure as the arm set up before the procedure can reduce operator radiation exposure. This measure is cost saving and

effective and should be considered for all programs aimed to reduce radiation exposure in the cath lab.

The role of the upper mobile shields in order to reduce operator radiation exposure has been observed in different previous studies with a possible dose reduction that in some cases reacheseven 90% of the dose (15-16). However, no study evaluated the role of dimensions and shape of the shield in term of operator radiation exposure. For the first time, in our study, we observed that a combined shield with a leaded glass and a leaded curtain is more effective for operator radioprotection compared to a full leaded glass shield. Two are the possible reasons of this differences: first of all the combined shield is probably more ergonomic and can be better adapted to the different patients, whereas the full glass shield sometimes cannot cover all the scattered radiation from the patient because of his fixed shape. Another possible explanation is the shield dimension. Amongthe centers involved in the study, the combined shield was 10 cm longeras compared to the full glass shield and this increase in dimension could have had a significant effect on operator shielding efficacy.

Some limitations of our study should be considered. Our study is a secondary analysis of the main studyand it was not pre-specified. The number of operators per group was limited (in particular for the comparison of the two upper mobile shields) which has prevented us from performing multivariable analysis to appraise the independent value of each of the two dose determinates investigated in this analysis. At the same time the sample size was small and the analysis limited to patients with acute coronary syndromes.Another important limitation of our study is the observational nature, and consequently our data should be confirmed in a dedicated randomized study.

Conclusions

In conclusion, the patient set-up during right transradial procedureswas identified as key factor associated to greater operator radiation exposure. In particular the patient right arm arrangement close to the right leg and the use of more ergonomic and longerupper shields were associated with a lower operator radiation exposure. Our findings emphasize the importance of implementing simple preventive measures to mitigate the extra risks of radiation exposure with right radial as compared with femoral access

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Figure Legends

Figure 1: Right arm set-up for transradial percutaneous coronary procedure. Two different right arm arrangements have been observed: a right arm positioning along the right leg (Panel A) and an external abducted arrangement (Panel B).

Figure 2: Upper mobile shields. In the centers involved in the study, two different upper mobile shields have been utilized: a combined leaded glass with leaded curtain screen (Panel A) and a full leaded glass shield (Panel B).

Figure 3: Positioning of the upper mobile shield. When the patient right arm is placed externally, the operator positioned the upper mobile shield laterally (Panel A) creating a gap between the shield and the radiation area that exposes operator to the scatter radiation coming from the patient (dotted triangle). Differently when the right arm is along the leg, the operator positioned the upper shield more medially (arrows)blocking most of the scatter radiation coming from the patient (Panel B).

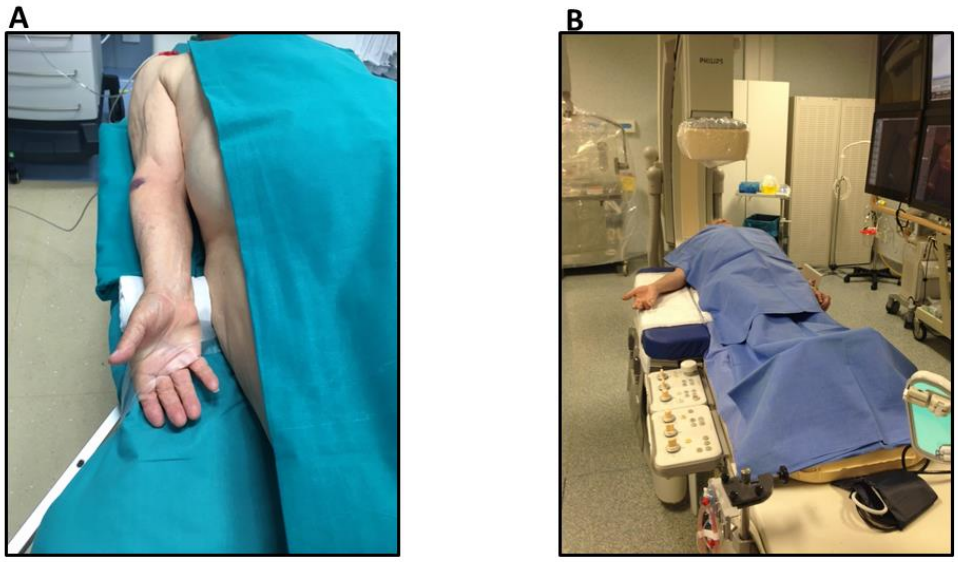


Figure 1

A

B

Figure 2

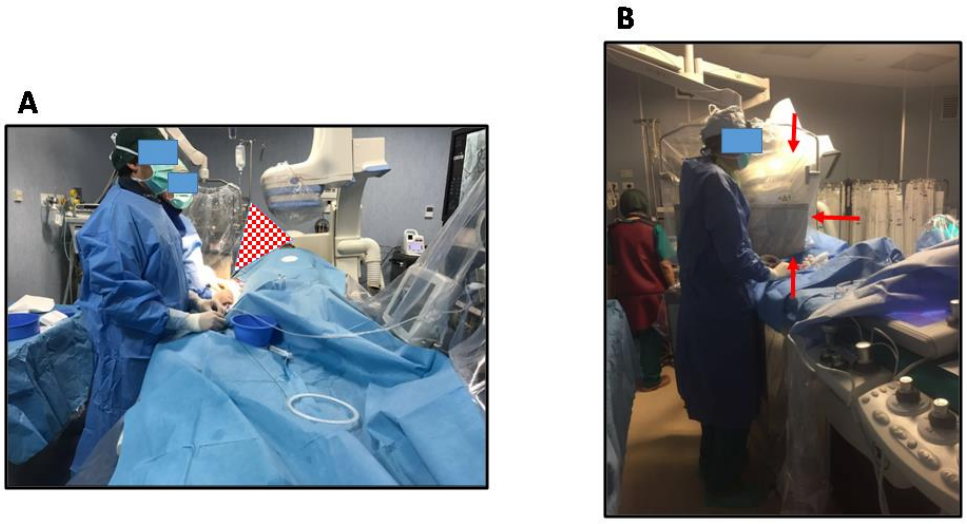
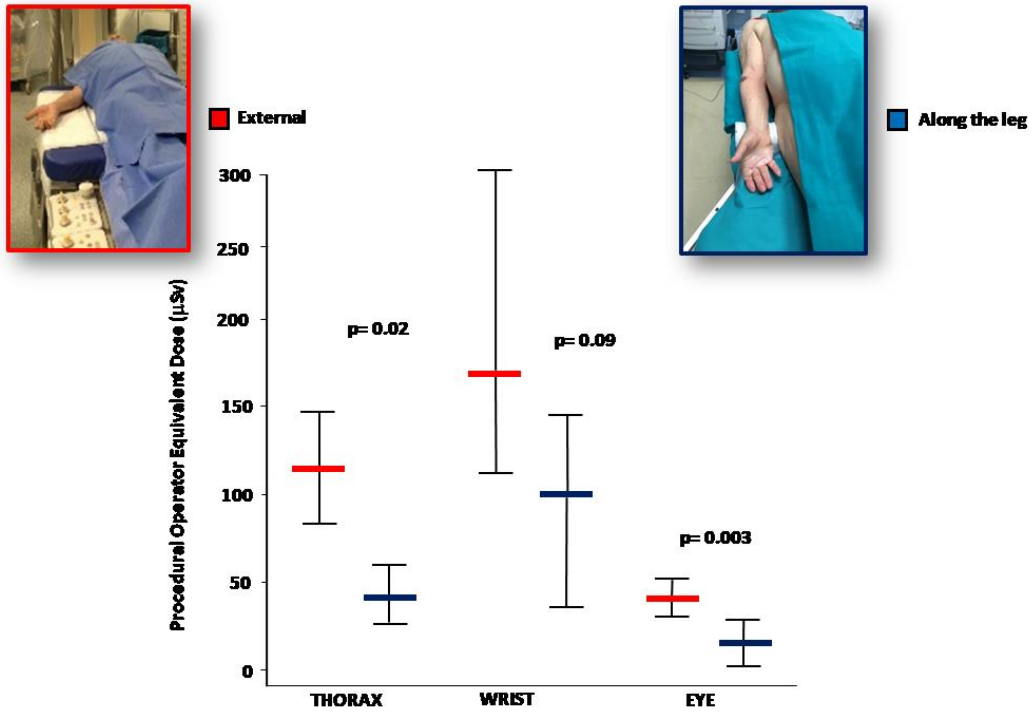


Figure 3



Graphical Abstract

Table I. Clinical and procedural characteristics.

	Group A (n= 6)	**Group B (n= 8)**	**P**
Patients (n)	69	68	
Procedures (n)	69	70	
Male (%)	49 (71)	53 (76)	0.46
Age (years)	66 ± 8	65 ± 6	0.71
Height (cm)	171 ± 5	168 ± 4	0.22
Weight (kg)	80 ± 7	77 ± 5	0.46
BMI	27 ± 2	27 ± 1	0.96
STEMI (%)	36 (52)	20 (29)	0.008
PCI (%)	55 (80)	60 (86)	0.48
Contrast (ml)	191 ± 40	175 ± 36	0.46
*Fluoroscopy time (min)	11 (8.5-13.2)	14 (11.5-16.8)	0.09
*DAP (Gy*cm^2)	93 (61-97)	97 (90-127)	0.17

Results expressed asmean with standard deviation or absolute numbers and percent in brackets.

*Medians with interquartile range

BMI: Body mass index; DAP: Dose Area Product; PCI: percutaneous coronary intervention; STEMI: ST elevation myocardial infarction

Group A: right arm close to the body

Group B: right arm abducted from the body

Table II. Radiation dose absorbed by operators during right radial access.

	Group A (n= 6)	**Group B (n= 8)**	**P**
Operator Dose (µSv)			
Thorax	46.1 (25.4-64)	110.4 (70.9-147.1)	0.02
Left wrist	97 (30-143)	168 (104-302)	0.09
Head	15.5 (6.1-26.9)	43.9 (35-54.5)	0.003
*Dose normalized by DAP(µSv/Cy*cm^2)*			
Thorax	0.55 (0.46-0.66)	0.91 (0.72-1.6)	0.03
Left wrist	1.05 (0.34-2.18)	1.75 (0.91-2.55)	0.30
Head	0.25 (0.071-0.28)	0.38 (0.27-0.61)	0.01

Results expressed as medians with interquartile range (25%-75%).

DAP: Dose Area Product

Group A: right arm close to the body

Group B: right arm abducted from the body

Highlights

- Determinants of operator radiation dose in transradial procedures are presented
- Patient set-up is a key factor associated to operator radiation exposure
- Patient right arm arrangement close to the right leg is associated with lower exposure
- The use of more ergonomic and longer upper shields is associated with lower exposure