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Randomized comparison of operator radiation exposure comparing transradial and transfemoral approach for percutaneous coronary procedures: rationale and design of the minimizing adverse haemorrhagic events by TRansradial access site and systemic implementation of angioX – RAdiation Dose study (RAD-MATRIX)

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ABSTRACT

Background: Radiation absorbed by interventional cardiologists is a frequently under-evaluated important issue. Aim is to compare radiation dose absorbed by interventional cardiologists during percutaneous coronary procedures for acute coronary syndromes comparing transradial and transfemoral access.
Methods: The randomized multicentre MATRIX (Minimizing Adverse Haemorrhagic Events by TRansradial Access Site and Systemic Implementation of angioX) trial has been designed to compare the clinical outcome of patients with acute coronary syndromes treated invasively according to the access site (transfemoral vs. transradial) and to the anticoagulant therapy (bivalirudin vs. heparin). Selected experienced interventional cardiologists involved in this study have been equipped with dedicated thermoluminescent dosimeters to evaluate the radiation dose absorbed during transfemoral or right transradial or left transradial access. For each access we evaluate the radiation dose absorbed at wrist, at thorax and at eye level. Consequently the operator is equipped with three sets (transfemoral, right transradial or left transradial access) of three different dosimeters (wrist, thorax and eye dosimeter). Primary end-point of the study is the procedural radiation dose absorbed by operators at thorax. An important secondary end-point is the procedural radiation dose absorbed by operators comparing the right or left radial approach. Patient randomization is performed according to the MATRIX protocol for the femoral or radial approach. A further randomization for the radial approach is performed to compare right and left transradial access.
Conclusions: The RAD-MATRIX study will probably consent to clarify the radiation issue for interventional cardiologist comparing transradial and transfemoral access in the setting of acute coronary syndromes.

1. Introduction

Interventional cardiologists are routinely and chronically exposed to ionizing radiations that are necessary to perform diagnostic and interventional coronary procedures. Moreover, some reports

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have shown that the radiation dose absorbed by interventional cardiologists is the greatest registered by any medical staff exposed to X-rays [1,2].

Even if radioprotection is an important issue for operators due to the long term stochastic risk of radio-induced cancer [3], this issue is often under evaluated.

1.1. Radiation risk for interventional cardiologists

Generally the stochastic risk related to radiation is an all-or-none phenomenon for any individual cell, but the greater the radiation exposure, the bigger number of injured cells [4]. Other than cancerous effects, such as cataract formation, were found to be statistically related to radio-exposure [5]. In a recent study [6] an increased risk for brain and neck tumours has been observed among physicians performing interventional procedures. Consequently, operators should apply all efforts to reduce their exposition to radiation dose according to the ALARA principle [3]: operators should maintain radiation exposure at a level that is "As Low As Reasonably Achievable", limiting the duration of exposure, increasing the distance from the radiation source and implementing the shielding equipment.

Radiation dose can be expressed in different ways: the Air Kerma is the amount of energy absorbed in a given mass of air, whereas the dose area product (DAP) is the absorbed dose of radiation across a given surface area. Generally DAP measurements are more accurate than using Air Kerma measurements for the estimation of patient radiation dose as DAP allows for variations in field size [7]. DAP consents a good estimation of the dose to the irradiated tissue and is an indicator for patient cancer risk. Differently Sievert is the unit used to express the biological damage to human tissues [8] and to evaluate the radiation dose absorbed by operators.

1.2. Transradial approach and clinical outcome

The number of percutaneous diagnostic and interventional percutaneous coronary procedures performed through transradial approach is progressively increasing worldwide [9]. The many reasons for this "radial boom" include a reduction in vascular complications [10,11] and a better patient comfort [12,13] compared to transfemoral approach. Moreover there is now a growing body of evidence that transradial approach might be associated with a better outcome in patients with acute coronary syndromes. The RIVAL [14] and the RIFLE-STEACS [15] trials are two randomized studies that showed a significant reduction in mortality with the transradial compared to transfemoral access in patients with acute ST elevation myocardial infarction. Also in non-ST elevation myocardial infarction there is a possible advantage in terms of better outcome for transradial approach even if data are conflicting. Indeed a better outcome associated with transradial approach in this subset of patients was shown in some observational studies [16] although it was not confirmed in the RIVAL study [14]. The MATRIX trial and possibly other randomized studies will clarify this issue.

1.3. Radiation exposure according to vascular access

Despite multiple advantages of transradial approach, a possible drawback of this access is a higher radiation exposure compared to transfemoral approach. The radiation risk might be increased both for the physician and for the patient even if data are conflicting [17–31]. Most of the studies evaluated only the radiation dose absorbed by patients and expressed it as DAP or Air Kerma (Table 1): some studies showed a significant increase in radiation dose for transradial compared to transfemoral approach, other studies showed no differences between the two approaches while in few studies a lower radiation dose for transradial approach was observed. The major bias of these studies is the observational design of the vast majority with only a few being randomized. To correct for the potential procedural biases, some authors performed a multivariate analysis [19,24,29,30], and in only one case the transradial approach was an independent predictor of increased radiation dose [29]. Another limitation of these studies is that most have assessed the fluoroscopy times, the DAP or the Air Kerma, that are only indirect measures of the radiation dose absorbed by operators. Only few studies [18,21,26,27,32] used dedicated operators' dosimeters and evaluated the radiation dose directly absorbed by operators when using different vascular accesses (Table 2). The majority of these

Table 1
Patient radiation dose in studies comparing transradial and transfemoral access.

Author (year)	Femoral (*n*)	Radial (*n*)	Design	Procedure	Right access (%)	DAP femoral	DAP radial	P	AK femoral	AK radial	P
Shah (2013)	870	240	Retr	Cor	85	50.19	60.40	0.003	670.3	805.4	0.02
Shah (2013)	512	74	Retr	PCI	89	153.95	196.49	0.02	2239	2795	0.03
Delewi (2013)	2950	6614	Prosp	Cor	NA	31	31	0.18	NA	NA	-
Delewi (2013)	2792	5056	Prosp	PCI	NA	79	73	<0.001	NA	NA	-
Michael (2013)	63	63	Rand	Cor	0	NA	NA	-	*1080	*1290	0.06
Michael (2013)	30	24	Rand	PCI	0	NA	NA	-	*1560	*1190	0.18
Rigattieri (2013)	243	1153	Retr	Cor + PCI	82	96.70	76.35	0.002	NA	NA	-
Jolly (2013)	2255		Rand	Cor + PCI	NA	51	53	0.828	†930	†1046	0.051
Lo (2012) Senior	25	25	Prosp	Cor	100	*22.4	*21.7	0.74	NA	NA	-
Lo (2012) Trainee	25	25	Prosp	Cor	100	*25.2	*25.4	0.90	NA	NA	-
Hibbert (2012)	361	203	Retr	Cor + PCI	NA	*123.3	194.1	<0.001	NA	NA	-
Mercuri (2011)	4190	1764	Prosp	Cor + PCI	NA	NA	NA	-	¶6.28	¶6.49	<0.001
Lehmann (2010)	842	624	Prosp	Cor + PCI	100	13.38	15.76	0.149	NA	NA	-
Brueck (2009)	512	512	Rand	Cor + PCI	NA	38.2	41.9	0.034	NA	NA	-
Achenbach (2008)	155	152	Rand	Cor + PCI	92	*3.199	*3.737	0.13	NA	NA	-
Lange (2006)	103	92	Rand	Cor	100	*13.1	*15.1	< 0.05	NA	NA	-
Lange (2006)	48	54	Rand	PCI	100	*51	*46.3	NS	NA	NA	-
Sandborg (2004)	40	36	Prosp	Cor	NA	33	45	0.0026	NA	NA	-
Sandborg (2004)	42	24	Prosp	PCI	NA	40	69	0.013	NA	NA	-
Geijer (2004)	114	55	Posp	Cor + PCI	98	54	51.9	NS	NA	NA	-
Larrazet (2003)	184	218	Prosp	PCI	NA	175	138	<0.001	NA	NA	-

DAP ($Gycm^2$) and AK (mGy) results are expressed as median.
AK: air kerma; Cor: diagnostic coronarography; DAP: dose area product; NA: not available; PCI: percutaneous coronary intervention; Prosp: prospective; Rand: randomized; Retr: retrospective.
* Results are expressed as mean.
† Data are available for 1445 patients.
¶ Results are expressed as mean logarithmically transformed air kerma.

Table 2
Operator radiation dose in studies comparing transradial and transfemoral access.

Author (year)	Femoral (*n*)	Radial (*n*)	Design	Procedure	Right access (%)	Dose femoral	Dose radial	P	Site
Michael (2013)	63	63	Rand	Cor	0	13 ± 10	26 ± 17	<0.01	Breast pocket
Michael (2013)	30	24	Rand	PCI	0	8.1 ± 7.1	13.9 ± 17.6	0.25	Breast pocket
Lo (2012) Senior	25	25	Prosp	Cor	100	6.1 ± 5.6	6.4 ± 4.7	0.85	Left clavicle
Lo (2012) Trainee	25	25	Prosp	Cor	100	8.8 ± 4.3	8.5 ± 6.5	0.86	Left clavicle
Brasselet (2008)	98	150	Prosp	Cor	NA	*13 (1–164)	*29 (1–195)	<0.001	Left arm
Brasselet (2008)	83	90	Retr	Cor + PCI	NA	*41 (2–360)	*69.5 (4–531)	<0.018	Left arm
Lange (2006)	103	92	Rand	Cor	100	32 ± 39	64 ± 55	< 0.001	Breast pocket
Lange (2006)	48	54	Rand	PCI	100	110 ± 115	166 ± 188	<0.05	Breast pocket
Sandborg (2004)	13	9	Prosp	Cor + PCI	NA	55	170	<0.01	Finger

Dose nμSv) results are expressed as mean.
Cor: diagnostic coronarography; NA: not available; PCI: percutaneous coronary intervention; Prosp: prospective; Rand: randomized.
* Results are expressed as median with interquartile range.

studies showed an increased operator radiation exposure with transradial compared to transfemoral access, although most data come from non randomized studies.

The main reasons for the possible higher radiation dose during transradial access are probably related to the more complicated catheter manipulation requiring prolonged fluoroscopy time and to the more unfavourable operator position, closer to X-ray source, especially for less skilled operators. These difficulties are easily overcome increasing the "radial competence" [33], but the magnitude of radiation exposure during transradial compared to transfemoral access for operators experienced in transradial approach is still unclear.

A final issue for the radiation dose in transradial approach is the "side arm effect". Most of the studies evaluating the operator and patient radiation dose during transradial and transfemoral percutaneous coronary procedures were performed using the right radial access. However in at least three previous studies [34–36], the left transradial approach compared to the right access was associated with reduced radiation dose for operators. The reason of this possible reduction in radiation dose is unknown until now even if a possible explanation might be a modest but significant reduction in fluoroscopy time [37].

At present there is only one study [18] comparing the left radial approach with the femoral access in terms of radiation dose absorbed either by the patients or by the operators. In this study a higher radiation dose for left radial compared to transfemoral approach has been observed, but this study has been performed only in patients with previous coronary artery by-pass.

1.4. Aim and end-points of the study

Aim of our study is to evaluate the radiation dose absorbed by operators during percutaneous coronary procedures in the setting of acute coronary syndromes comparing the transradial and the transfemoral approach. The radiation exposure during right or left transradial procedures is also compared.

The primary end-point of the study is the procedural radiation dose absorbed by operators and detected by thermo luminescent dosimeters placed at thorax level of the operators. Key secondary end-points are the procedural radiation dose measured at the operator's wrist and eye. Other secondary end-points are the radiation dose normalized by DAP and by fluoroscopy time, fluoroscopy times and DAP values.

1.5. Study design and population

The MATRIX (Minimizing Adverse Haemorrhagic Events by TRansradial Access Site and Systemic Implementation of angioX) trial (NCT01433627) has been designed to compare the clinical outcome of patients with acute coronary syndromes treated invasively according to the access site (transfemoral vs. transradial) and to the anticoagulant therapy (bivalirudin vs. heparin). It is a large-scale, multicenter, prospective, open-label trial, conducted at approximately 100 sites in Europe in centers performing either transradial and transfemoral approach for percutaneous coronary procedures and will enrol more than 8,000 patients.

All diagnostic or interventional procedures performed in selected centers by operators involved in the MATRIX trial are included in this sub-study without exclusion criteria. The operator and center selection is performed according to the operator experience and to the recruiting volume: only highly experienced operators and high volume recruiting centers are included in this substudy. Moreover in the operators' selection for our sub-study, we also required that operators can perform equally right or left transradial access.

Operator radiation exposure is assessed using three sets of three dedicated dosimeters for the femoral approach, for the right radial approach and for the left radial approach.

Effective doses delivered to patients are expressed as DAP and measured in $Gycm^2$. The DAP is directly measured by the collimator of the angiographic system. The duration of the procedure is expressed in minutes of fluoroscopy time.

1.6. Dosimeters description

The study uses lithium fluoride thermo luminescent dosimeters with a range of linearity from 1 μGy to 10 Gy. All dosimeters, contained in a plastic package for water and dust risk, are easy to wear and do not interfere with operator comfort during the procedures. In order to facilitate delivery and collection of data, dosimeter's label clearly indicate operator's code, access site (femoral, right or left radial) and body destination (eye, throax or wrist) (Fig. 1). The dosimeter's design is different according to it placement:

1. Thorax dosimeter: this dosimeter consists of a case (badge) containing two thermoluminescent detectors under two filter of various materials in a symmetrical configuration, so it can be worn in each side. The thorax dosimeter is placed in the breast pocket outside the lead apron.
2. Wrist dosimeters: dosimeters for the wrist weigh less than 2 grams and can be incorporated in a waterproof flexible package and worn under surgical gloves (Fig. 1).
3. Eye dosimeter: this dosimeter contains three different filters, have a weight < 3 grams and is placed on the head cup (Fig. 1).

According to the randomization of the MATRIX trial, operators locate the three dosimeters on the left wrist, at mid thorax level, in the breast pocket outside the lead apron and at eye level outside the lead glasses (Fig. 2). At the end of the study the dosimeters will be send to TECNORAD co. (Verona, Italy) to measure the radiation dose absorbed by operators. The radiation dose obtained for each dosimeter is then divided for the number of procedures in whom the dosimeter has been employed in order to obtain the mean radiation dose per procedure.

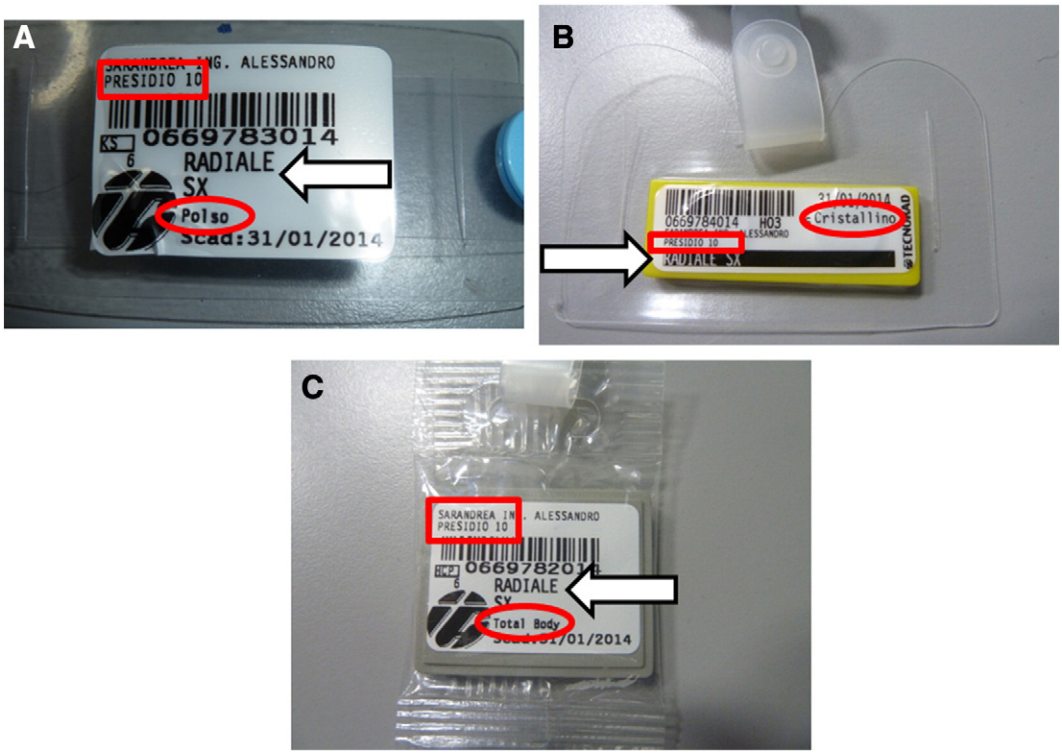

Fig. 1. Three different dosimeters are employed: wrist dosimeter (A), eye dosimeter (B) and thorax dosimeter (C). Each dosimeter is labelled with the site access (arrow), the operator code (square) and with the body destination (circle).

1.7. Randomization and statistical considerations

Patient randomization is performed according to the MATRIX protocol for the femoral or radial approach using a Web-based system. A further randomization for the radial approach is performed according to the identification (ID) number of patient: odd ID numbers are assigned to right radial whereas even ID numbers are assigned to left radial access. The data analysis will be performed as "intention to treat," and consequently operators do not need to remove their dosimeters if they need to switch from transradial to transfemoral approach or vice versa. Considering that only highly experienced operators are involved in this sub-study we will expect a very low rate of cross over from one to the other vascular access.

Fig. 2. Placement of the three dosimeters. The operator is equipped with three dosimeters per access: one dosimeter is placed at left wrist, another is fixed at the breast pocket and the third on the head cup close to the eye.

The sample size was estimated on the basis of the primary end-point (procedural radiation dose absorbed at thorax by operators comparing transradial vs. transfemoral approach). The primary non inferiority hypothesis of this study is that the radial approach does not cause an increase of radiation dose to the operator compared to transfemoral approach. Considering that our dosimeters measure the cumulative radiation dose, the sample size is calculated for the number of dosimeters needed rather than for the number of procedures. Moreover to avoid potential procedural biases (for example balancing long vs. short procedures), each dosimeter should be used in at least 12 procedures per access. According to a previous study evaluating the thorax operator radiation dose for transradial compared to transfemoral approach [26], showing a procedural mean dose of 142 microSievert for a single percutaneous coronary diagnostic plus interventional procedure through transfemoral approach we determined that 26 dosimeters (13 per access) would provide a power of 80% to calculate a non inferiority margin of 25 microSievert (18% difference) with a one-sided alpha level of 0.05. Since each set of dosimeters will be used in at least 12 patients a minimum of 312 patients will be enrolled in the present study.

1.8. Percutaneous coronary procedure

The coronary procedure is performed according to the MATRIX protocol and according to the standard of each operator involved in the study: the sheath selection (long vs. short, hydrophilic vs. non hydrophilic), the catheter curve employed and the use of adjunctive

tools (manual thrombus-aspiration, intracoronary ultrasound) is left to the operator's choice.

Standard operator radio-protection in all procedures is ensured using a lead apron (two layers of 0.25 mm lead equating to 0.5 mm in the front of the operator), a thyroid lead collar, leaded glasses (0.5 mm leaded-equivalent for each), under-table leaded flaps attached to the table, and an upper mobile leaded glass suspended from the ceiling.

2. Conclusions

Considering the controversial data on transradial and transfemoral approach in terms of radiation dose absorbed by interventional cardiologists, the RAD-MATRIX study will give more detailed information on this issue, collecting data on radiation exposure at various parts of the body.

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