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## Efficacy of RADPAD protective drape during coronary angiography

Although there have been many improvements over the past decades in optimizing coronary angiography, ionizing radiation remains an important issue. Chronic exposure to low-dose radiation as experienced by interventional cardiologists confers an increased risk for skin damage, eye lens opacities or cataracts, and various malignant diseases [1–4].

In any coronary angiography, the amount of radiation exposure to the operator is determined among other factors by the body mass index (BMI) of the patient, by the duration of the fluoroscopic procedure, and by the respective experience of the operator.

The RADPAD (Worldwide Innovations & Technologies, Inc., Kansas City, Kan.) is a sterile surgical drape containing bismuth and antimony. When positioned correctly on the patient between the image intensifier and the operator, the RADPAD has been shown to reduce the effect of scatter radiation on the operator. Utilization of the RADPAD has already been shown to reduce radiation exposure in routine percutaneous coronary intervention (PCI) procedures, complex PCI procedures [5], peripheral endovascular procedures [6], cardiac resynchronization therapy device implantation [7, 8], and fluoroscopically guided electrophysiological procedures [9].

We sought to assess the efficacy of RADPAD shields in reducing the radiation dose experienced by operators during routine diagnostic coronary angiography via transfemoral access.

### Patients and methods

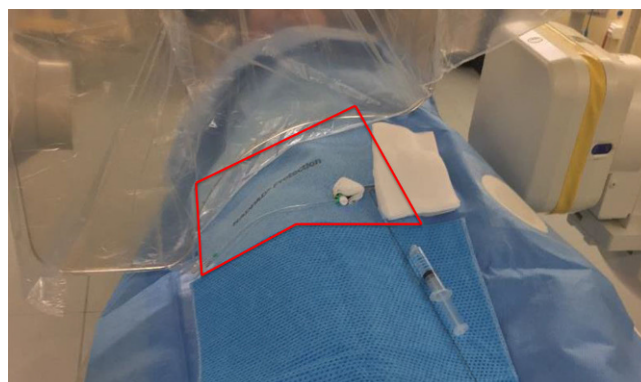
In total, 60 consecutive patients due to undergo elective coronary angiography were identified and randomized in a 1:1 pattern to have their procedures performed with and without the RADPAD drape. Patients with a history of coronary bypass surgery (CABG) were excluded.

During the angiography, standard shielding equipment was used, including a lead coat, thyroid shield, and protective lenses, in addition to a lead shield suspended from the ceiling between the image intensifier and the

operator. All operators had undergone radiation awareness courses and were trained in the optimal placement of the RADPAD drape.

All coronary angiographies were performed from the right femoral artery. The RADPAD was positioned superior to the sheath insertion point, immediately below the lead shield suspended from the ceiling between the image intensifier and the operator (Fig. 1). All coronary angiographies were performed using the same angulations, the same number of frames, and the same settings in the same biplane cardiology intervention suite (Artis zee, Siemens, Germany).

The dosimeter was placed on the upper, outer aspect of the left arm of the operator, at the level of the mid humerus of the operator. Dosimetric measurements were obtained using an Unfors



**Fig. 1** ◀ Positioning of RADPAD. This figure shows the correct positioning of the RADPAD. The shield is placed on the patient's leg around the area of sheath insertion (red lines)

Table 1 Baseline characteristics				
	Total 60 pts	RADPAD 30 pts	No RADPAD 30 pts	<i>p</i>
Age (years)	62.5 ± 12.8	63.8 ± 11.6	61.2 ± 14	0.44
Women	22 (37%)	10 (33.3%)	12 (40%)	0.79
BMI (kg/m <sup>2</sup> )	27.8 ± 4.9	27.7 ± 4.24	27.9 ± 5.53	0.85

Data are expressed as numbers, mean ± SD  
*BMI* body mass index, *pts* patients

Table 2 Radiation dose				
	Total 60 pts	RADPAD 30 pts	No RADPAD 30 pts	<i>p</i>
Screening time (s)	103.5 ± 65.4	102 ± 86	105 ± 36	0.89
DAR (cGy/cm <sup>2</sup> )	1438.9 ± 703.1	1336.9 ± 581.6	1541.0 ± 803.7	0.26
Dose (μSv)	15.6 (Q1:4.4, Q3:31.2)	8.0 (Q1:3.2, Q3:20.1)	19.6 (Q1:7.1, Q3:37.7)	0.02
Dose/ST (μSv/min)	9.2 (Q1:2.4, Q3:19.0)	5.8 (Q1:2.0, Q3:15.8)	11.0 (Q1:4.3, Q3:19.3)	0.08

Data are expressed as numbers, mean ± SD or median and 1st quartile (Q1) and 3rd quartile (Q3)  
*DAR* dose–area ratio, *pts* patients

Table 3 Radiation dose according to BMI				
		RADPAD	No RADPAD	<i>p</i>
Screening time (s)	BMI < 25 kg/m <sup>2</sup>	81 ± 27	116 ± 35	0.03
	BMI > 25 kg/m <sup>2</sup>	110 ± 99	98 ± 36	0.62
DAR (cGy/cm <sup>2</sup> )	BMI < 25 kg/m <sup>2</sup>	846.3 ± 236.3	1,027.5 ± 453.2	0.32
	BMI > 25 kg/m <sup>2</sup>	1515 ± 568	1,838 ± 819	0.15
Dose (μSv)	BMI < 25 kg/m <sup>2</sup>	2.2 (Q1:2.1, Q3:9.0)	6.4 (Q1:3.7, Q3:16.9)	0.15
	BMI > 25 kg/m <sup>2</sup>	12.9 (Q1:4.5, Q3:21.0)	32.7 (Q1:17.1, Q3:39.0)	0.006
Dose/ST (μSv/min)	BMI < 25 kg/m <sup>2</sup>	1.8 (Q1:1.2, Q3:8.0)	3.9 (Q1:2.4, Q3:9.9)	0.49
	BMI > 25 kg/m <sup>2</sup>	8.6 (Q1:2.4, Q3:17.4)	15.5 (Q1:9.6, Q3:27.0)	0.02

Data are expressed as numbers, mean ± SD or median and 1st quartile (Q1) and 3rd quartile (Q3)  
*DAR* dose area ratio, *BMI* body mass index, *pts* patients

EDD meter (Unfors Instruments AB, Billdal, Sweden). The dosimeter was commenced at the start of the procedure, and the dose was recorded immediately after the end of the procedure. Screening times (ST) and dose–area ratios (DAR) for each individual procedure were collected prospectively. The study was approved by the local ethics committee of the Charité – Universitätsmedizin Berlin, and every patient gave informed consent to this study.

For continuous data with normal distribution, an independent-samples *t* test

was used. Otherwise, the nonparametric Mann–Whitney *U* test was used. Continuous data with normal distribution are reported as mean ± SD, or otherwise as median and quartiles. A *p* value of <0.05 was accepted as statistically significant.

## Results

During the study period, 60 patients were successfully randomized to undergo diagnostic angiography with RADPAD or no shield (no RADPAD). The mean age of the study group was 62.5 ± 12.8 years and

37% were female. The baseline characteristics of the study population according to the randomization groupings were similar (Table 1).

There was no significant difference in the two main determinants of radiation exposure in both groups: the screening times (102 ± 86 s for the RADPAD group vs. 105 ± 36 s for the control group, *p* = 0.89) and BMI (27.7 ± 4.24 kg/m<sup>2</sup> for the RADPAD group vs. 27.9 ± 5.53 kg/m<sup>2</sup> for the control group, *p* = 0.85).

Furthermore, there was no difference in the DAR (1336.9 ± 581.6 cGy/cm<sup>2</sup> for the RADPAD group vs. 1541.0 ± 803.7 cGy/cm<sup>2</sup> for the control group, *p* = 0.26) between the two patient groups (Table 2).

The primary operator radiation dose was significantly lower in the RADPAD group at 8.0 μSv (Q1: 3.2, Q3: 20.1) compared with 19.6 μSv (Q1: 7.1, Q3: 37.7) for the control group (*p* = 0.02).

The dose rate, however, was not significantly lower in the RADPAD group at 5.8 μSv/min (Q1: 2.0, Q3: 15.8) compared with 11.0 μSv/min (Q1: 4.3, Q3: 19.3) for the control group, (*p* = 0.08; Table 2).

Next we analyzed operator radiation dose according to the BMI. We therefore divided the patients into two different BMI groups. The analysis revealed a significant dose reduction in the BMI group of >25 kg/m<sup>2</sup> (RADPAD group 12.9 μSv [Q1: 4.5, Q3: 21.0] vs. 32.7 [Q1: 17.1, Q3: 39.0] for the control group, *p* = 0.006), whereas in the BMI group of <25 kg/m<sup>2</sup> (RADPAD group 2.2 μSv [Q1: 2.1, Q3: 9.0] vs. 6.4 μSv [Q1: 3.7, Q3: 16.9] for the control group, *p* = 0.15) there was no statistically significant reduction (Table 3).

We then analyzed the effects of the RADPAD in reducing radiation exposure to the operator. Total radiation exposure to primary operators was reduced using the RADPAD by 59% overall. In the BMI group of >25 kg/m<sup>2</sup> there was a 61% reduction in radiation exposure, whereas in the BMI group of <25 kg/m<sup>2</sup> there was a 66% reduction (Table 3; Fig. 2).

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## Efficacy of RADPAD protective drape during coronary angiography

### Abstract

**Background.** Ionizing radiation is an integral part of percutaneous coronary angiographies. Chronic exposure to low-dose radiation confers a risk for skin damage, eye lens opacities or cataracts, and malignant diseases to staff in the catheter laboratory. The RADPAD is a sterile surgical drape that reduces the effect of scatter radiation on the operator. We sought to assess the efficacy of RADPAD shields in reducing radiation dose experienced by operators during routine diagnostic coronary angiography.

**Patients and methods.** Sixty consecutive patients due to undergo elective coronary angiography were randomized in a 1:1 pattern to have their procedures performed with and

without the RADPAD drape in situ. Dosimetry was performed on the left arm of the primary operator.

**Results.** There was no significant difference in the two main determinants of radiation exposure in both groups: the screening times ( $102 \pm 86$  s for the RADPAD group vs.  $105 \pm 36$  s for the control group,  $p = 0.9$ ) and body mass index (BMI;  $27.7 \pm 4.2$  kg/m<sup>2</sup> for the RADPAD group vs.  $27.9 \pm 5.5$  kg/m<sup>2</sup> for the control group,  $p = 0.8$ ). Moreover, there was no difference in the dose–area ratio ( $1337 \pm 582$  cGy/cm<sup>2</sup> for the RADPAD group vs.  $1541 \pm 804$  cGy/cm<sup>2</sup> for the control group,  $p = 0.3$ ) between the two patient groups. The primary operator radiation dose was significantly

lower in the RADPAD group at  $8.0$  μSv (Q1: 3.2, Q3: 20.1) compared with  $19.6$  μSv (Q1: 7.1, Q3: 37.7) for the control group ( $p = 0.02$ ).

**Conclusion.** The RADPAD significantly reduces radiation exposure to primary operators during routine diagnostic coronary angiography in patients with a BMI > 25 kg/m<sup>2</sup>. It reduces total radiation exposure to primary operators by 59%, and the radiation exposure rate by 47%.

### Keywords

Radiation protection · Radiation exposure · Coronary angiography · Femoral artery · Body mass index

## Wirksamkeit des RADPAD-Strahlenschutztschutzes bei Koronarangiographien

### Zusammenfassung

**Hintergrund.** Trotz der Verwendung von Strahlenschutzkleidung besteht durch die Streustrahlung eine Strahlenbelastung für den interventionell tätigen Kardiologen. RADPAD ist ein steriles Strahlenschutztschutzes, die die Belastung der Streustrahlung für den Untersucher reduziert. Die Autoren untersuchten, ob sich bereits bei diagnostischen Koronarangiographien die Belastung durch Streustrahlung für den Untersucher durch die Verwendung des RADPAD reduzieren lässt.

**Methoden.** Hierzu wurden 60 Patienten, bei denen eine diagnostische Koronarangiographie mit standardisiertem Untersuchungsablauf durchgeführt wurde, 1:1 randomisiert in eine Gruppe mit und eine ohne RADPAD.

**Ergebnisse.** Beide Gruppen zeigten hinsichtlich der Durchleuchtungszeit ( $105 \pm 36$  s in der Kontrollgruppe bzw.  $102 \pm 86$  s in der Strahlenschutztschutzesgruppe,  $p = 0,9$ ) und des Body-Mass-Index ( $27,9 \pm 5,5$  kg/m<sup>2</sup> in der Kontrollgruppe bzw.  $27,7 \pm 4,2$  kg/m<sup>2</sup> in der Strahlenschutztschutzesgruppe,  $p = 0,98$ ), welche die maßgeblichen Faktoren für die kumulative Streustrahlungsdosis sind, keine signifikanten Unterschiede. Auch hinsichtlich des Dosis-Flächen-Produkts (DFP) ergab sich zwischen beiden Gruppen kein Unterschied: Das DFP betrug in der Kontrollgruppe  $1541 \pm 804$  cGy/cm<sup>2</sup>, in der Strahlenschutztschutzesgruppe  $1337 \pm 582$  cGy/cm<sup>2</sup> ( $p = 0,3$ ). Die einwirkende Strahlenäquivalenzdosis erwies sich jedoch in Strahlenschutztschutzesgruppe mit  $8,0$  μSv (Q1: 3,2; Q3: 20,1) als signifikant

geringer im Vergleich zu  $19,6$  μSv (Q1: 7,1; Q3: 37,7) in der Kontrollgruppe ( $p = 0,02$ ).

**Schlussfolgerung.** Durch die Verwendung des Strahlenschutztschutzes wurde im Vergleich zur Kontrollgruppe die Strahlenbelastung für den Untersucher bereits bei diagnostischen Koronarangiographien bei Patienten mit einem BMI > 25 kg/m<sup>2</sup> signifikant reduziert. Insgesamt konnte die Strahlenbelastung des Untersuchers (–59 %) und die Strahlenbelastungsrate (–47 %) reduziert werden.

### Schlüsselwörter

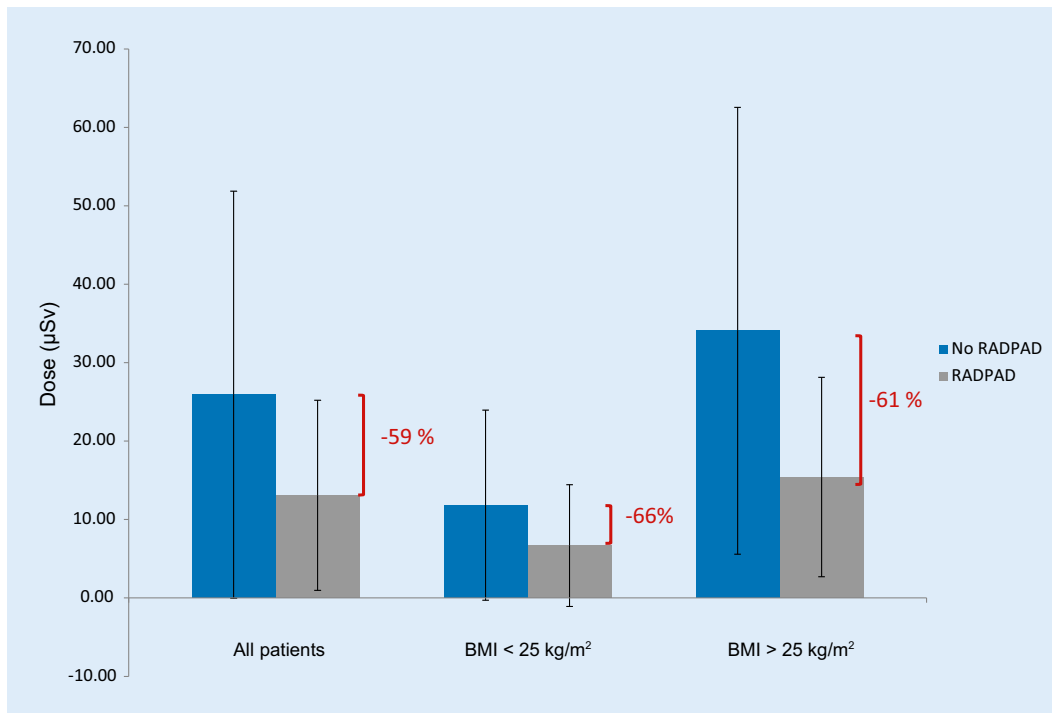
Strahlenschutz · Strahlenexposition · Koronarangiographie · A. femoralis · Body-Mass-Index

## Discussion

The number of cardiologic interventional procedures has dramatically increased in the past decade [10] exposing the interventional cardiologist to more cumulative radiation exposure. Minimizing radiation exposure to patients and staff members is, therefore, important to interventional cardiologists. Even with standard protection equipment – including a lead coat, thyroid shield, and protective lenses, in addition to a lead shield

suspended from the ceiling between the image intensifier and the operator – and techniques to minimize scatter radiation, including performing fluoroscopic imaging at the lowest available pulse rate, minimizing the number and duration of cine runs, minimizing the cine frame rate, and minimizing image amplification and collimation to areas of interest during PCI [4], radiation dose for the interventional cardiologists and the catheterization laboratory members remains a task of paramount importance.

Usage of the RADPAD has already been shown to reduce radiation exposure in complex PCI procedures with prolonged screening times [5]. The present randomized trial shows, however, for the first time that a sterile lead-free drape significantly reduces the radiation exposure to the interventional cardiologist already during routine diagnostic coronary angiography performed via the right femoral artery access with short screening times. Moreover, the study confirms that the use of the RADPAD is feasible



**Fig. 2** ◀ Dose reduction. Primary operator dose reduction in all patients with a BMI of <25 kg/m<sup>2</sup> and in patients with a BMI of >25 kg/m<sup>2</sup>. Data are expressed as mean ± SD. Red labels percent dose reduction

and does not prolong the procedure as demonstrated by the short time employed for fluoroscopy.

This study had certain limitations. Radiation levels were measured only on the operator's chest. It is conceivable that differences in radiation doses between the two groups may have been different from those observed if radiation levels had been measured at various sites including the left eye, the thyroid regions, and the left wrist.

## Conclusion

This study showed that by using the RADPAD protection, total radiation exposure to primary operators could be reduced by half (59%) the amount without prolonging the procedure, despite the short screening time of a diagnostic coronary angiography. We therefore recommend, despite the additional costs involved (currently € 45, not reimbursed by the German health-care system), the integration of the RADPAD in diagnostic coronary angiography in patients with a BMI of >25 kg/m<sup>2</sup>. This probably also applies to non-coronary artery interventions, such as endomyocardial biopsy in patients with cardiomyopathies of heart failure with preserved ejection fraction

either via a transradial or a transfemoral approach [11–13], and to electrophysiological ablation procedures [14].

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## Compliance with ethical guidelines

**Conflict of interest.** B. Kherad, T. Jerichow, F. Blaschke, M. Noutsias, B. Pieske, C. Tschöpe, and F. Krackhardt declare that they have no competing interests.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Declaration of Helsinki of 1975 (in its most recently amended version). Informed consent was obtained from all patients included in the study.

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## PxC-Studie: Jeder Vierte würde das lokale Krankenhaus in Schieflage finanziell unterstützen

**Viele kommunale Kliniken sind vom wirtschaftlichen Aus bedroht. Obwohl sie in der Bevölkerung keine hohe Priorität bei der Auswahl für einen medizinischen Eingriff genießen, wäre ein Viertel der Deutschen bereit, für eine am Wohnort gelegene Klinik aus eigenen Mitteln eine Sonderabgabe zu leisten.**

Nur knapp vier von zehn Patienten wären bereit, mehr als 50 Kilometer zu fahren, um sich in einer Klinik einem medizinischen Eingriff zu unterziehen. 32 Prozent würden 30 bis 50 Kilometer in Kauf nehmen, 22 Prozent bis zu 30 Kilometer, fünf Prozent würden in das nächstgelegene Krankenhaus gehen. Das ergibt eine bevölkerungsrepräsentative Befragung der Strategieberatung PwC. „Wie weit würden Sie fahren, um ein Krankenhaus zu besuchen, das Ihren persönlichen Anforderungen an die Qualität des Hauses entspricht?“, lautete die konkrete Fragestellung.

Diese mit fünf Prozent gering ausgeprägte Bereitschaft zur Inanspruchnahme des lokalen, meist kommunalen Krankenhauses korreliert mit der oft klammen Finanzsituation der betreffenden Häuser. Nach eigener Aussage wären 18 Prozent der Bevölkerung bereit, einmalig bis zu zehn Prozent ihres monatlichen Nettoeinkommens für den Erhalt der kommunalen Klinik zu spenden, wenn diesem aufgrund seiner schlechten wirtschaftlichen Lage die Schließung drohen würde, sieben Prozent gingen sogar über diese Messlatte hinaus. Grundsätzlich nicht bereit für eine freiwillige Spende an die Klinik erklärten sich 40 Prozent der Befragten – bei den Senioren über 65 Jahre sind es 50 Prozent. 35 Prozent der Bevölkerung gibt an, sich eine solche finanzielle Samariteraktion schlicht nicht leisten zu können – hier führen wiederum die Senioren mit 38 Prozent.

### Unikliniken bei Qualität gefragt

Generell scheint es sich beim Erhalt eines kommunalen Krankenhauses in wirtschaftlicher Schieflage eher um eine emotionale denn eine qualitätsorientierte Angelegenheit zu handeln. Diese Häuser sind zwar Teil der regionalen medizinischen Versorgung, die höchsten Qualitätsstandards erwarten dort – wie auch bei den Häusern in konfessioneller Trägerschaft aber – nur fünf Prozent der Befragten. 19 Prozent sehen die Qualitäts-

führerschaft bei privaten Krankenhäusern, 64 Prozent nehmen die Unikliniken bei den höchsten Qualitätsstandards in die Pflicht. Bei der Klinikwahl ist im Falle eines einfachen Eingriffs für 61 Prozent ein hohes Maß an Sauberkeit und Hygiene das Top-Kriterium, auf Rang fünf rangiert die Hausarzt Empfehlung mit 29 Prozent. Bei schweren medizinischen Sachverhalten sowie bei chronischen Erkrankungen ist für die Deutschen mit 71 Prozent bzw. 62 Prozent bei der Klinikwahl das Vorhandensein eines großen Teams von Top-Ärzten und Spezialisten führendes Auswahlkriterium – in beiden Fällen kommt die Hausarzt Empfehlung (je 31 Prozent) auf Platz vier.

### Vertrauen in die regionale Klinik

62,7 Prozent der Befragten gaben an, eine im Krankenhaus erhaltene Diagnose noch einmal mit ihrem Hausarzt zu besprechen. 86 Prozent von ihnen – Mehrfachnennungen waren möglich – verfahren so, weil ihnen die Meinung ihres „Arztes des Vertrauens“ wichtig ist. Jeweils elf Prozent gaben an, dass sie Klinikärzten nicht vertrauten bzw. dass diese die Diagnose nicht so gut erklären könnten wie der Hausarzt. Nahezu paradox mutet es an, dass immerhin 73 Prozent der Umfrageteilnehmer angeben, dass sie „ihrem“ Krankenhaus vertrauen – 20 Prozent von ihnen haben sogar vollstes Vertrauen. Bedenken oder Ängste äußern nur sechs Prozent. Ebenso ist mit 63 Prozent die Mehrheit der Bevölkerung davon überzeugt, dass im nächstgelegenen Krankenhaus das Wohl des Patienten stärker zählt als wirtschaftliche Überlegungen.

**Quelle: Ärzte Zeitung  
(www.aerztezeitung.de)**