# Role of Experience, Leadership and Individual Protection in the Cath Lab – A Multicenter Questionnaire and Workshop on Radiation Safety

Die Bedeutung interventioneller Erfahrung, Führung und individueller Schutzmaßnahmen im Katheterlabor – Ergebnisse einer multizentrischen Befragung mit Strahlenschutzkurs

Authors

E. Kuon<sup>1</sup>, K. Weitmann<sup>2</sup>, W. Hoffmann<sup>2</sup>, M. Dörr<sup>3</sup>, A. Hummel<sup>3</sup>, M. C. Busch<sup>3</sup>, S. B. Felix<sup>3</sup>, K. Empen<sup>3</sup>

Affiliations

<sup>1</sup> Division of Cardiology, Klinik Fraenkische Schweiz, Ebermannstadt, Germany

<sup>2</sup> Institute for Community Medicine, University Medicine, Greifswald, Germany

<sup>3</sup> Division of Internal Medicine, University Medicine, Greifswald, Germany

### Key words

- radiation safety
- heart
- coronary angiography
- efficacy studies
- education
- QA/QC

### **received** 10.1.2015 **accepted** 12.4.2015

#### **Bibliography**

DOI http://dx.doi.org/ 10.1055/s-0034-1399662 Published online: 10.6.2015 Fortschr Röntgenstr 2015; 187: 899–905 © Georg Thieme Verlag KG Stuttgart - New York -ISSN 1438-9029

## Correspondence

Dr. Eberhard Kuon Abteilung für Kardiologie, Klinik Fraenkische Schweiz Feuersteinstrasse 2 91320 Ebermannstadt Germany Tel.: ++ 49/(0)91 94/5 52 52 Fax: ++ 49/(0)91 94/55 43 99 eberhard.kuon@gmx.de

# Zusammenfassung

**Ziel:** Die Strahlenexposition in der invasiven Kardiologie ist erheblich. Wir untersuchten die Akzeptanz von Strahlenschutzvorrichtungen und den Einfluss von Erfahrung, Teamleitung und technischer Ausstattung auf die Strahlenschutzbemühungen im klinischen Alltag.

**Material und Methoden:** 115 Kardiologen (27 Zentren) beantworteten einen Fragebogen und erhoben multiple Dosisparameter im Verlauf von 10 Koronarangiografien (KA) vor und 3,1 Monate nach einem 90-min. Kurs in strahlenreduzierenden Techniken.

Ergebnisse: Die Kursteilnehmer erzielten signifikante mediane Absenkungen des Dosisflächenprodukts (DFP: von 26,6 auf 13,0 Gy × cm<sup>2</sup>), der Bilder- (-29%) und Serienanzahl (-18%), des radiografischen DFP/Bild (- 32%), des fluoroskopischen DFP/Sek. (-39%) und der Durchleuchtungszeit (-16%). Die Mehrebenen-Analyse ergab niedrigere DFPs mit sinkendem Körpergewichtsindex  $(-1,4 \text{ Gy} \times \text{cm}^2 \text{ per } \text{kg}/\text{m}^2)$  und Alter  $(-1,2 \text{ Gy} \times \text{cm}^2/10 \text{ J.})$ , für weibliches Geschlecht  $(-5,9 \, \text{Gy} \times \text{cm}^2)$ , Kursteilnahme der Kardiologen  $(-16,1 \text{ Gy} \times \text{cm}^2)$  und zusätzlich  $(-9,4 \text{ Gy} \times \text{cm}^2)$ des Teamleiters, für interventionelle Erfahrung  $(-0.7 \text{ Gy} \times \text{cm}^2/1000 \text{ KA})$  sowie ältere konventionelle Katheteranlagen (-6,6 Gy  $\times$  cm<sup>2</sup>). Strahlenschutzmittel wurden in folgender Häufigkeit verwendet: Mantel (100%), Scheibe (95%), Untertischlamellen längs/quer (94%/69%), Schilddrüsenschutz (89%), Brille (28%), Patienten-Oberschenkelabdeckung (19%), Fußschalterabdeckung (7%), Handschuhe (3%) und Helm (1%). Schlussfolgerung: Strahlenschutzmaßnahmen werden in der täglichen Routine unzureichend umgesetzt. Kardiologen unterschiedlichsten Erfah-

rungsstandes profitierten von unserem Strahlen-

schutzkurs, vor allem im Falle der Kursteilnahme

des Teamleiters.

# Abstract

**Purpose:** Radiation exposure in invasive cardiology remains considerable. We evaluated the acceptance of radiation protective devices and the role of operator experience, team leadership, and technical equipment in radiation safety efforts in the clinical routine.

**Materials and Methods:** Cardiologists (115 from 27 centers) answered a questionnaire and documented radiation parameters for 10 coronary angiographies (CA), before and 3.1 months after a 90-min. mini-course in radiation-reducing techniques.

**Results:** Mini-course participants achieved significant median decreases in patient dose area products (DAP: from 26.6 to  $13.0 \,\text{Gy} \times \text{cm}^2$ ), number of radiographic frames (-29%) and runs (-18%), radiographic DAP/frame (-32%), fluoroscopic DAP/s (-39%), and fluoroscopy time (-16%). Multilevel analysis revealed lower DAPs with decreasing body mass index ( $-1.4 \text{ Gy} \times \text{cm}^2 \text{ per } \text{kg}/\text{m}^2$ ), age  $(-1.2 \text{ Gy} \times \text{cm}^2/\text{decade})$ , female sex  $(-5.9 \text{ Gy} \times \text{cm}^2)$ , participation of the team leader  $(-9.4 \,\text{Gy} \times \text{cm}^2)$ , the mini-course itself ( $-16.1 \text{ Gy} \times \text{cm}^2$ ), experience  $(-0.7 \text{ Gy} \times \text{cm}^2/1000 \text{ CAs throughout the interven-})$ tionalist's professional life), and use of older catheterization systems ( $-6.6 \text{ Gy} \times \text{cm}^2$ ). Lead protection included apron (100%), glass sheet (95%), lengthwise (94%) and crosswise (69%) undercouch sheet, collar (89%), glasses (28%), cover around the patients' thighs (19%), foot switch shield (7%), gloves (3%), and cap (1%).

**Conclusion:** Radiation-protection devices are employed less than optimally in the clinical routine. Cardiologists with a great variety of interventional experience profited from our radiation safety workshop – to an even greater extent if the interventional team leader also participated. **Key Points:** 

Radiation protection devices are employed less than optimally in invasive cardiology.

### Kernaussagen:

- Strahlenschutzmaßnahmen sind in der invasiven Kardiologie unteroptimal umgesetzt.
- Der vorgestellte Strahlenschutz-Minikurs erwies sich als hocheffizient.
- Kardiologen unterschiedlichsten Erfahrungsstandes profitierten von ihm: erheblich mehr im Falle einer Teilnahme des Teamleiters.
- Interventionelle Erfahrung spielte eine untergeordnete Rolle für die erzielte Dosisreduktion.
- Daher sollten Auszubildende wie auch erfahrene Kollegen durch Kursangebote zu eigenverantwortlichem Strahlenschutz ermutigt werden.
- Introduction

# Widespread application of radiation-intensive cardiovascular tests - primarily myocardial scintigraphy, computed tomography, coronary angiography (CA) and percutaneous coronary intervention (PCI) [1-3] - has contributed since 1982 to a 6-fold increase in the individual annual average medical effective dose (ED) in the United States: to ~ 3.0 mSv, over and above 2.4 - 3.2 mSv of background radiation [2, 4, 5]. Interventional procedures at more than a few catheterization sites are evidently performed in a manner remarkably similar to techniques pioneered decades ago [6], and the resulting ED levels vary greatly: e.g., 0.1 - 20 mSv for CA and 2-57 mSv for PCI [3, 5, 7, 8]. As a result of observable patient radiation hazards - for example, erythema, ulceration, and radioderma [9, 10] - concerns have grown regarding unwarranted justification and inappropriate optimization, as well as lack of adherence to quality control [2, 3, 9]. Supported by data from radiation workers [11] and atomic bomb survivors [12], the linear no-threshold model assumes that no dose may be regarded as harmless [2, 3]. Chronically exposed cardiologists are susceptible to excess risk of cellular redox imbalance [13], spinal pain and cataracts, as well as brain tumors [10, 14 - 16]. Recent reports, in addition, suggest that female interventionalists are inclined to left-sided breast cancer [16, 17]. With annual exposition at ED levels of ~ 5 mSv (up to individual values of ~ 19 mSv) - i.e., three times the levels of radiologists and nuclear physicians - their lifelong professional ED could reach or even exceed 100 mSv [2, 14, 18], equivalent to 1.0% and 0.5% of the lifetime attributable risks (LAR) for cancer incidence and death, respectively [9]. LAR increases by a factor of 2 for acute radiation exposure, by ~ 3 for children, by ~ 1.4 for women and by ~ 0.5 for the elderly (>80 years) [2, 18]. Recently, a representative multicenter course entitled "Encourage Less Irradiating Cardiologic Interventional Techniques" (ELICIT) proved effective in achieving significant short-term and ongoing two-year, long-term dose reductions for CA [19-21], a well-accepted intervention marker for radiation safety practice [21 – 23]. Until now, however, few insights have been gained in awareness, attitudes or remedial efforts in the radiation issue from the interventionalist's standpoint. Our ELICIT questionnaire sub-study consequently focused on operator experience, radiation safety knowledge as well as acceptance and implementation of "as low as reasonably achievable" (ALARA) principles. We matched this individual feedback with documented key dose parameters [21] to evaluate the role of interventional experience (in terms of CAs performed throughout the interventionalist's professional life) and team leadership as possible determinants of multicenter course efficacy.

- The presented radiation-safety mini-course was highly efficient.
- Cardiologists at all levels of experience profited from the minicourse – considerably more so if the team leader also took part.
- Interventional experience was less relevant for radiation reduction.
- Consequently both fellows and trainers should be encouraged to practice autonomy in radiation safety.

## **Citation Format:**

Kuon E, Weitmann K, Hoffmann W et al. Role of Experience, Leadership and Individual Protection in the Cath Lab – A Multicenter Questionnaire and Workshop on Radiation Safety. Fortschr Röntgenstr 2015; 187: 899–905

# Methods

# Definitions

The total air kerma is the cumulative dose to the air at the interventional reference point ( $K_{A, R}$ ; unit: Gray [Gy]). The skin dose includes backscatter in the upper skin layers and represents the most relevant characterization of deterministic skin lesions. The dose area product (DAP; unit: Gy × cm<sup>2</sup>) is the product of  $K_{A, R}$  and the irradiated skin area. The effective dose (ED; unit: Sievert [Sv]) is the sum of all equivalent doses to exposed organs and characterizes future cancer risks. DAP-to-ED conversion factors have been calculated at ~0.20 mSv/Gy × cm<sup>2</sup> for the male thoracic region [7, 18].

## Study design, setting, and patients

We designed our work to be a voluntary study and received approval from the local institutional ethics committee. All patients and interventionalists were encoded. In accordance with German National Radiation Safety Regulations, each interventionalist had completed both basic and advanced theoretical 20-hour courses in radiation protection, an 8-hour special course in fluoroscopicguided intervention, and annual 1-hour refresher courses. From 2003 to 2009, 177 interventionalists at 32 German cardiac centers performed 10 consecutive elective CAs - each by femoral access before and after a 90-min. mini-course conducted by one experienced cardiologist [21]. The sub-study presented herein deals with a sub-cohort of 115 of these interventionalists - 15 of them representing team leaders - at 27 centers, who attended the mini-course and completed an additional questionnaire on radiation safety. Of all centers, 21 employed traditional image-intensifier catheterization systems, and 6 used advanced flat-panel acquisition technology. Each interventionalist used the same equipment throughout the program and, immediately after questionnaire completion prior to the mini-course, received anonymized feedback on his/her individual baseline results. Documentation occurred before and at a median of 3.1 months after both the questionnaire and the mini-course, and included total DAP, radiographic (DAP<sup>R</sup>) and fluoroscopic (DAP<sup>F</sup>) fractions, fluoroscopy time, and number of radiographic frames and runs. DAP<sup>R</sup>/frame and DAP<sup>F</sup>/s were calculated as parameters of dose intensity.

The interactive workshop included a standardized oral Power-Point presentation, which illustrated the anonymized baseline results and addressed the following dose-reduction factors: (1) essential time on beam; (2) consistent collimation – fluoroscopy-free or intermittent by short pedaling – to the region of interest: i. e., training of coronary intubation in the "buttonhole technique"; (3) copper filtering; (4) adequate low-level pulse rates and detector entrance dose levels; (5) lower irradiating angulations and only adequate magnification; (6) full inspiration during radiography; (7) long source-to-skin and short patient-to-detector distances and (8) sufficiently rested operators. Each of these steps toward improved radiation safety practice was discussed in depth with published data [21, 23, 24], demonstrated in the cath lab and/or illustrated by educational videos.

### Statistical analysis

We compared patient data before and after the mini-course by the Mann-Whitney U test (median values and interquartile range of metric data) or the chi-square test ( $\chi^2$ , categorical data) at a two-tailed significance level of 0.05 (SAS 9.1 Cary, NC, USA). We applied generalized linear latent and mixed models from STATA (SE 10.1, Texas, USA) to analyze by a multi-level approach the change in radiation dose parameters as a function of influencing key variables on the following levels: patient (age, sex, body mass index), operator (mini-course participation, experience per 1000 CAs performed throughout the interventionalist's professional life) and center (workshop participation of the team leader, advanced system). Experience data were lacking for 2 operators. Finally, a total of 2260 sets of patient data were nested in 113 operators, which we in turn nested in 27 centers.

# Results

#### ▼

Prior to the mini-course, the interventionalists regarded consistent collimation to the region of interest to be most effective toward irradiation-reducing CA, followed by shorter radiographic time on beam, lower irradiating angulations and shorter fluoroscopy times. They judged the esteem granted to ALARA principles to be highest by themselves, lower by their colleagues, and lower even by the International Commission on Radiological Protection (ICRP) and German national medical societies (**• Table 1**). One third of the operators had been professionally engaged in invasive cardiology for <5 years, one third for 5 – 10 years and one

third for >10 years. The median individual yearly workload was 350 CAs and 100 PCIs; the median lifelong experience was 2500 CAs and 500 PCIs (**•** Table 2). The Spearman correlation factors for estimated vs. definitely measured DAPs, runs, frames and fluoroscopy times due to CAs at baseline were 0.49, 0.43, 0.41 and 0.37, respectively. The importance accorded by interventionalists to table-attached and individual lead protection devices reflected their individual use in the daily routine: i.e., as concerns aprons, overcouch glass sheets and longitudinal undercouch sheets. Seen by participants as less important were transverse undercouch sheets, collars, glasses, covers around patients' thighs, foot-switch shields, gloves and caps (> Table 3). The reduction from 26.6 to 13.0 Gy  $\times$  cm<sup>2</sup> (-51 %) of the median patient overall DAP for CAs performed by workshop participants resulted from enhanced fluoroscopic (-39%) and radiographic (-32%) collimation and additionally from shorter fluoroscopic (-16%) and radiographic (-29%) time on beam, the latter due to fewer (-18%) and shorter (-17%) radiographic runs (**• Table 4**, • Fig. 1). Over and above validation of mini-course efficacy and of higher dose parameters with increasing BMI, age and male sex - multilevel analysis (> Table 5) in the presented ELICIT questionnaire sub-study revealed significant additional influence of interventional team-leader participation on center level  $(-9.4 \,\text{Gy} \times \text{cm}^2)$ . Operator experience per 1000 CAs performed throughout the interventionalist's professional life resulted in a lower DAP ( $-0.7 \text{ Gy} \times \text{cm}^2$ ), fewer frames and runs and shorter fluoroscopy times (-11s). Advanced flat-panel systems were associated with a higher DAP and longer times on beam.

### Discussion

▼

This multicenter field study at 27 cardiac catheterization laboratories clearly shows that in the clinical routine both insufficient awareness of radiation risks and inappropriate acceptance of radiation protective devices remain a serious challenge. Operator experience proved to be less relevant (-3% per 1000 CAs, performed throughout the interventionalist's professional life) for

e less relevent	a serious challenge. Operator vant (-3% per 1000 CAs, per- ionalist's professional life) for						
ean ± SD	Table 1       Estimated values for ra-						
	diation exposure due to coronary						
8±16	angiography, for the dose reduc-						
2 ± 19	tion potential and for the impor-						
3 ± 2	nles						
0±314	pics.						
9±4	Tab. 1 Schätzwerte für die						
3.4±1.2	Strahlenexposition und das Dosis-						
	reduktionspotential im Verlauf ei-						
5±16	ner Koronarangiografie und die						
2 ± 15	ALAKA-PHILIZIPIEN DEIGEMESSENE						
7 ± 12	beaeutung.						

	n <sup>1</sup>	median (IQR)	mean ± SD						
estimated individual values for dose parameters during coronary angiography									
dose area product [Gy × cm <sup>2</sup> ]	103	25 (16 – 35)	28 ± 16						
fluoroscopic fraction [%]	77	30 (20 – 40)	32 ± 19						
fluoroscopy time [min]	82	2.5 (2 – 3)	3 ± 2						
radiographic frames [n]	60	530 (300 – 700)	530±314						
radiographic runs [n]	76	9 (7 – 10)	9 ± 4						
length of run [s]	94	3.5 (2.5 – 3.5)	3.4 ± 1.2						
estimated reduction of radiation exposure [%] due to coronary angiography by optimized									
collimation to region of interest	92	20 (13 – 30)	25±16						
fewer radiographic frames	92	20 (10 – 30)	22 ± 15						
lower irradiating angulations	91	15 (10 – 20)	17 ± 12						
shorter fluoroscopy times	90	10 (10 – 20)	16±11						
estimated value [010] <sup>2</sup> attached to ALARA principles by									
herself/himself	103	8 (6 – 9)	7 ± 2						
colleagues	102	7 (5 – 8)	6 ± 2						
International Commission on Radiological Protection	92	5 (4 – 9)	6 ± 3						
german medical societies	95	5 (3 – 7)	5 ± 3						

ALARA: as low as reasonably achievable; IQR: interquartile range; SD: standard deviation.

ALARA: so niedrig wie sinnvollerweise realisierbar; IQR: interquartiler Bereich; SD: Standardabweichung.

<sup>1</sup> Responses from 115 questionnaires.

Antworten in 115 Fragebögen.

<sup>2</sup> Range between "no" (0) and "extreme" (10) importance.

Entscheidungsbereich: "keine" (0) ... "extreme" (10) Bedeutung.

### Table 2 Experience in invasive cardiology before the mini-course.

Tab. 2 Erfahrung in der invasiven Kardiologie vor dem Minikurs.

	coronary a	ngiography		percutaneous coronary intervention			
experience	n <sup>1</sup>	median (IQR)	mean (SD)	n <sup>1</sup>	median (IQR)	mean ± SD	
number of interventions							
individual [lifelong]	113	2500 (800 – 5000)	3639 ± 3676	109	500 (100 – 1500)	1260 ± 1766	
individual [year]	111	350 (200 – 500)	390 ± 234	108	100 (50 – 200)	145 ± 140	
institutional [year]	93	2300 (1800 – 3200)	2534 ± 999	91	800 (600 – 1100)	873 ± 427	
years [% operators]	<1[9]	1 – 2 [9]	3 – 5 [16]	5 – 10 [33]	10–20[24]	>20[9]	

IQR: interguartile range; SD: standard deviation.

IQR: interquartiler Bereich; SD: Standardabweichung.

<sup>1</sup> Responses from 115 guestionnaires

Antworten in 115 Fragebögen

### Table 3 Radiation protection devices in invasive cardiology.

Tab. 3 Strahlenschutzvorrichtungen und -maßnahmen in der invasiven Kardiologie.

	individual use [%]			attached	attached importance [010] <sup>1</sup>		
lead protection	n <sup>2</sup>	median (IQR)	mean ± SD	n <sup>2</sup>	median (IQR)	mean ± SD	
apron	111	100 (100 – 100)	100 ± 0	101	10 (10 – 10)	$10 \pm 0$	
glass sheet	111	100 (100 – 100)	95 ± 18	96	10 (10 – 10)	10 ± 1	
UCS – longitudinal	109	100 (100 – 100)	94 ± 25	96	10 (9 – 10)	9 ± 2	
collar	110	100 (100 – 100)	89 ± 30	99	10 (10 – 10)	9 ± 2	
UCS – transversal	104	100 (0 – 100)	69 ± 46	93	10 (5 – 10)	8 ± 4	
eyeglasses	109	0 (0 - 80)	28 ± 42	95	5 (2 – 10)	5 ± 3	
cover around patients' thighs	108	0 (0 – 10)	19±36	81	5 (1 – 7)	5 ± 3	
foot switch shield	107	0 (0 – 0)	7 ± 25	92	2 (0 – 5)	3 ± 3	
gloves	109	0 (0 – 0)	3 ± 15	93	2 (0 – 4)	2 ± 3	
сар	109	0 (0 – 0)	1 ± 8	92	0 (0 – 2)	1 ± 2	

IQR: interquartile range; SD: standard deviation; UCS: undercouch lead sheet.

IQR: interquartiler Bereich; SD: Standardabweichung; UCS: Untertisch-Bleilamellen.

<sup>1</sup> Range between "no" (0) and "extreme" (10) importance.

Entscheidungsbereich: "keine"(0) ... "extreme"(10) Bedeutung. <sup>2</sup> Responses from 115 questionnaires.

Antworten in 115 Fragebögen.

	before mini-course	after mini-course	change (%)	p-value
operators [n]	115	115		
patients [n]	1150	1150		
centers [n]	27	27		
patient age [years]	65.9 (58.4 – 72.8)	66.0 (58.2 - 72.5)		0.960
female [%]	34.1	38.3		< 0.040
body mass index [kg/m <sup>2</sup> ]	27.5 (25.0 – 30.5)	26.9 (24.5 - 30.1)	- 2	< 0.001
DAP [Gy × cm <sup>2</sup> ]	26.6 (16.2 - 42.0)	13.0 (7.8 – 20.8)	- 51	< 0.001
$DAP^{R}[Gy \times cm^{2}]$	20.0 (12.2 – 31.7)	9.6 (5.5 – 15.8)	- 52	< 0.001
$DAP^{F}[Gy \times cm^{2}]$	5.1 (2.6 – 9.8)	2.5 (1.3 – 5.0)	- 51	< 0.001
DAP <sup>R</sup> /frame [mGy × cm <sup>2</sup> ]	30.1 (20.9 – 41.5)	20.5 (12.9 – 29.9)	- 32	< 0.001
DAP <sup>F</sup> /s [mGy × cm <sup>2</sup> ]	32.5 (20.5 – 47.2)	19.9 (11.8 – 33.9)	- 39	< 0.001
frames [n]	678 (514 – 900)	484 (359 – 653)	- 29	< 0.001
runs [n]	11 (9 – 13)	9 (8 – 11)	- 18	< 0.001
frames/run [ <i>n</i> ]	62.6 (53.1 – 73.7)	52.2 (42.3 - 64.5)	- 17	< 0.001
fluoroscopy time [s]	150 (100 – 258)	126 (84 – 210)	- 16	< 0.001

Table 4 Patients' radiation dose parameters for mini-course participants.

Tab. 4 Mediane (interquartiler Bereich) Patientendosisparameter vor und nach dem Minikurs.

Values are *n* or median (interquartile range). DAP: dose area product; DAP<sup>R/F</sup>: radiographic/fluoroscopic DAP.

DAP: Dosisflächenprodukt; DAPR/F: radiografisches/fluoroskopisches DAP.

radiation reduction in the cath lab than the presented ELICIT mini-course itself (-51%). Participation of the interventional team leader significantly enhanced course efficacy on the center level. The median overall DAP for CAs achieved at baseline in this sub-study of questionnaire participants was comparable to actual German and French national registry values of 21.1 and



**Fig. 1** Median results from ten coronary angiographies, achieved by each participant before (I: black bars) and after the mini-course (II: white bars). Ranking of overall course efficacy from best (1) to less than optimal practice (115) after the mini-course (**a**) with assignment of the most important influencing factors on operator level: i. e., radiographic (**b**) and fluoroscopic (**c**) dose intensities and the number of radiographic frames (**d**).

Abb. 1 Mediane Ergebnisse (von jeweils 10 Koronarangiografien) der 115 Teilnehmer vor (I: schwarze Säulen) und nach dem Minikurs (II: weiße Säulen): Gliederung von bester (1) zu suboptimaler (115) Umsetzung strahlenreduzierender Techniken nach dem Minikurs (a) mit untersucherspezifischer Zuordnung der wichtigsten Einflussfaktoren: Dosisintensität während Radiografie (b) und Durchleuchtung (c) sowie radiografische Bilderanzahl (d).

Table 5 Multilevel analysis of all dose parameters regarding influencing factors on the patient, operator and center level.

<b>Tab. 5</b> Memobelien-Allaryse aller Dosisparameter byl. Elimassiaktoren auf ratienten-, ontersucher-, Zentramsebene.	Tab. 5	Mehrebenen-Anal	lyse aller Dosisparameter l	bgl. Einflussfaktorer	n auf Patienten-, Unte	rsucher-, Zentrumsebene.
--	--------	-----------------	-----------------------------	-----------------------	------------------------	--------------------------

		patients (n = 2260)		operators (n = 113)		centers (n = 27)		
	constant	BMI kg × m²	age per decade	<b>sex</b> ೆ	after mini-course	operator experience	team leader attendance	advanced system
							(n = 15)	(n=6)
DAP [Gy × cm <sup>2</sup> ]	-13.0	+1.4	+1.2	+ 5.9	-16.1	-0.7	-9.4	+6.6
p-value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.030
$DAP^{R}$ [Gy × cm <sup>2</sup> ]	-4.7	+ 1.0	+0.7	+4.6	-12.1	-0.4	-12.6	+2.6
p-value	0.057	< 0.001	< 0.004	< 0.001	< 0.001	< 0.002	< 0.001	< 0.030
DAP <sup>F</sup> [Gy × cm <sup>2</sup> ]	-5.2	+0.4	+0.5	+ 0.3	-4.0	-0.3	-1.9	+ 1.0
p-value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.020	0.290
DAP <sup>R</sup> /F [mGy × cm <sup>2</sup> ]	-14.9	+ 1.5	+0.7	+ 4.7	-8.9	-0.2	-7.6	+ 1.5
p-value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.030	< 0.001	0.088
DAP <sup>F</sup> /s [mGy × cm <sup>2</sup> ]	-13.2	+ 1.7	+0.4	+ 5.3	-13.8	-0.1	-3.4	-2.3
p-value	< 0.001	< 0.001	0.226	< 0.001	< 0.001	0.666	0.366	0.406
frames [n]	+718	+ 1	+13	+ 63	-197	-7	-159	+ 43
p-value	< 0.001	0.345	< 0.002	< 0.001	< 0.001	< 0.030	< 0.001	0.071
runs [n]	+ 10.0	+0.02	+0.2	+ 0.5	-1.8	-0.1	-0.9	+0.2
p-value	< 0.001	0.082	< 0.001	< 0.001	< 0.001	< 0.010	< 0.02	0.685
frames/run [n]	+60.0	-0.1	+0.2	+ 3.6	-8.2	-0.1	-3.1	-3.2
p-value	< 0.001	0.203	0.593	< 0.001	< 0.001	0.570	0.320	0.940
fluoroscopy time <sup>1</sup> [s]	+ 80.2	+ 1	+ 2	+11	-48	-11	-7	+ 83
p-value	< 0.030	0.116	< 0.001	0.127	< 0.001	< 0.001	0.673	< 0.001

BMI: per kg/m<sup>2</sup>; sex: 0 = 9,  $1 = \sigma$ ; operator experience: per 1000 CAs, performed throughout professional life; for all other parameters (mini-course participation, team leader attendance, advanced system):  $0 = n_0$ , 1 = yes. Projected DAP for CA (BMI 28.0 kg/m<sup>2</sup>, 70 years, 9), performed by a participant with experience of 200 CAs after the mini-course (participating team leader) with a traditional system: DAP [Gy × cm<sup>2</sup>] =  $-13.0 + (28 \times 1.4) + (7 \times 1.2) + (1 \times -16.1) + (0.2 \times -0.7) + (1 \times -9.4) = 9.0$ . BMI: body mass index; CA: coronary angiography; DAP<sup>R</sup>/F: radiographic DAP/frame; further abbreviations as in **O Table 4**.

BMI: per kg/m<sup>2</sup>; Geschlecht:  $0 = 9, 1 = \sigma$ ; Untersuchererfahrung: ... pro 1000 bislang erbrachte CA; für Kursteilnahme, Teamleiter-Teilnahme, moderne Katheteranlage: 0 = nein, 1 = ja. Kalkuliertes DAP einer CA (BMI 28,0 kg/m<sup>2</sup>, 70 J., 9), erbracht durch einen Kursteilnehmer mit Erfahrung über 200 CA nach dem Kurs (mit Teilnahme des Teamleiters) an einem konventionellen Kathetersystem: DAP [Gy × cm<sup>2</sup>] = -13,0 + (28 × 1,4) + (7 × 1,2) + (1 × -16,1) + (0.2 × -0,7) + (1 × -9,4) = 9,0. CA: Koronarangiografie; DAP<sup>R</sup>/F: radiografisches DAP/Bild. Weitere Abkürzungen wie in **> Tab. 4**.

<sup>1</sup> Analysis calculated only on the operator level.

Nur auf Untersucherebene kalkulierte Analyse.

27.2 Gy × cm<sup>2</sup>, respectively [25, 26]. Great DAP differences, however, existed among course participants even after the program, with a range from 3.8 to 44.0 Gy × cm<sup>2</sup> ( $\circ$  Fig. 1), equivalent to ED values from ~ 1 to ~ 9 mSv.

The presented ELICIT questionnaire disclosed a discrepancy in mutual perception concerning ALARA compliance among radiology commissions, medical societies [2, 9, 27] and practicing colleagues. These interventional cardiologists claimed to appreciate ALARA principles more in the daily routine than they conceded to their colleagues, national medical societies and - most unexpectedly to the International Commission on Radiological Protection (ICRP; • Table 1). We can only speculate whether the majority of interventionists indeed fail to appreciate the aims and efforts of national and international commissions [9, 27 - 29] toward radiation protection, or whether they simply do not perceive adequate support by supervisory authorities in the implementation of radiation-reducing conventions in the cath lab [21, 27-29]. Since calculated LAR for cataracts [9, 18] and brain malignancy [2, 9, 14, 15] increase considerably upon failure to use protective devices, acceptance and use of only 28 % for lead glasses, 89 % for thyroid-protection collar and 94-95% for under-/overcouch shielding is unjustified in the clinical routine. Neglect alone to use a lead collar results in a 3-fold individual ED [30]. Consistent closure of radiation leakage, indeed, is highly effective in obtaining a 93% reduction in overall operator scatter radiation beneath recommended lead clothing: i.e., toward a fluoroscopic 0.2 µSv/h level [23], which is lower than natural background exposure [2, 5, 14].

Program participants, irrespective of experience, readily recognized that considerable potential, in the form of certain interventional techniques, existed for radiation reduction (> Table 1, • Fig. 1): i.e., improved collimation, adequate image quality, heart rate adaptive pulsing, and reduced time on beam [21, 23]. In addition, estimated DAP, radiographic runs, frame numbers and fluoroscopy times correlated quite well with actually achieved values. BMI, male sex and age were positively correlated to dose-related parameters, owing to the increasing complexity of expected coronary heart disease [19, 20]. Higher patient doses upon use of advanced flat-panel technology can be explained by a tendency to employ higher pulse rates and/or greater pre-set detector-dose intensities during radiography [21, 24]. Consistent translation of heart-rate adaptive and advanced detector settings, however, has recently enabled reduction of radiographic and fluoroscopic dose intensities by 70 and 80%, respectively [24]. Although fluoroscopy time may characterize interventional experience in invasive cardiology, it is of minor relevance for total DAP - at least during CA. Fluoroscopy contributes to ~ 20% of the total radiation exposure, and radiographic dose intensity amounted to 20 to 30 times the fluoroscopy intensity (> Table 4) [24]. The influence of the operator's individual experience and team leadership on radiation safety performance was a compelling focus of this study. Multilevel analysis indeed disclosed a significant but marginal decrease in DAP by  $0.7 \text{ Gy} \times \text{cm}^2$  per lifelong-performed 1000 CAs, equivalent to only 3% of the baseline level. This experience parameter reduced the number of radiographic frames, runs and DAP<sup>R</sup>/frame within a range of 0.8 to 1.3%. Participation of the team leader in fact significantly enhanced course efficacy on the center level toward a remarkable additional median DAP reduction of 9.4 Gy × cm<sup>2</sup>. Consequently, her/his integration in any educational radiation safety initiative is certainly beneficial: all the more, considering the relatively slight importance of operator experience.

Implementation of radiation safety guidelines and ALARA principles will be less efficient if they are not translated into interventionalists' language and if implementation is not in harmony with their autonomous attitudes. This represents a joint challenge for cardiology societies, radiation safety commissions, supervising authorities and physicists toward setting achievable objectives that require unreserved educational cooperation with the practicing cardiology community in every cath lab. Whereas benchmarking registries [25, 26] and single-center approaches [22, 31] typically evaluate fluoroscopy time, DAP, and/or skin dose, our ELICIT workshop focuses on specific reasons for suboptimal practice, indicates main individual challenges and promotes the following: (1) disclosure of daily attitudes and technical settings by understandable evaluation of relevant dose parameters; (2) definition of educational benchmarks; (3) enhanced motivation for optimization by pseudonymized feedback; (4) competitive comparison of individual performance with various strategies, as implemented by widely accepted cardiac centers; and (5) qualification of participants towards autonomous reduced-radiation improvements and situation-adapted operation of pre-selectable interfaces.

This ELICIT sub-study for the cohort of interventionalists who completed both the course program and the presented questionnaire is not without limitations. It cannot establish long-term course efficacy, since it was verifiable over a follow-up period of only 3.1 months. Recently, however, a multicenter 2-year follow-up ELICIT survey revealed a 64% overall DAP reduction and validated long-lasting and ongoing efficacy of the mini-course [20]. A follow-up questionnaire evaluation would have been interesting to elucidate the individual lead protection performance after the mini-course. Not least, our feedback data on dose intensities do not allow differentiation among the effects of collimation, detector entrance dose or pulse rates.

# Clinical relevance

- 1. The evaluation of operator attitudes revealed insufficient levels of both acceptance and use of radiation-protective clothing and devices in invasive cardiology.
- 2. The ELICIT course program was highly effective.
- 3. With focus on complex individual challenges, cardiologists at all levels of interventional experience profited from the mini-course – even considerably more if the interventional team leader also participated.
- 4. Interventional experience proved to be of minor relevance for radiation reduction in the cath lab.
- 5. The cardiology community should consequently encourage and train wherever necessary both fellows and trainers toward autonomy in radiation safety.

#### References

- 1 *Einstein AJ, Weiner AD, Bernheim A et al.* Multiple testing, cumulative radiation dose and clinical indications in patients undergoing myocardial perfusion imaging. JAMA 2010; 304: 2137–2144
- 2 Picano E, Vañó E, Rehani MM et al. The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology. Eur Heart J 2014; 35: 665–672
- 3 *Einstein AJ, Berman DS, Min JK et al.* Patient-centered imaging: shared decision making for cardiac imaging procedures with exposure to ionizing radiation. J Am Coll Cardiol 2014; 63: 1480–1489

- 4 National Council on Radiation Protection and Measurements. Ionizing Radiation Exposure of the Population of the United States. Report No. 160. Bethesda, MD: National Council on Radiation Protection and
- Measurements; 2009 5 *Einstein AJ*. Effects of radiation exposure from cardiac imaging: how good are the data? J Am Coll Cardiol 2012; 59: 553–565
- 6 Smilowitz NR, Balter S, Weisz G. Occupational hazards of interventional cardiology. Cardiovasc Revasc Med 2013; 14: 223 228
- 7 Pantos I, Patatoukas G, Katritsis DM et al. Patient radiation doses in interventional cardiology procedures. Curr Cardiol Rev 2009; 5: 1–11
- 8 *Kuon E, Felix SB, Weitmann K et al.* ECG-gated coronary angiography enables submillisievert imaging in invasive cardiology. Herz 2014; 39 [Epub ahead of print]
- 9 Cousins C, Miller DL, Bernardi G et al. Radiological protection in cardiology. ICRP publication 120. Ann ICRP 2013; 42: 1 – 125
- 10 Chambers CE. Mandatory radiation safety training for fluoroscopy imaging: a quality improvement priority or unnecessary oversight? JACC Cardiovasc Interv 2014; 7: 391–393
- 11 *Cardis E, Vrijheid M, Blettner M et al.* The 15-Country Collaborative Study of Cancer Risk among Radiation Workers in the Nuclear Industry: estimates of radiation-related cancer risks. Radiat Res 2007; 167: 396–416
- 12 Preston DL, Shimizu Y, Pierce DA et al. Studies of mortality of atomic bomb survivors. Report 13: solid cancer and noncancer disease mortality: 1950–1997. Radiat Res 2012; 178: AV 146–172
- 13 *Russo GL, Tedesco I, Russo M et al.* Cellular adaptive response to chronic radiation exposure in interventional cardiologists. Eur Heart J 2012; 33: 408–414
- 14 *Knuuti J, Järvinen J.* CardioPulse. Radiation exposure and the risk of cancer for interventional cardiologists and electrophysiologists. Eur Heart J 2014; 35: 603–604
- 15 *Roguin A*. CardioPulse. Radiation in cardiology: can't live without it!: using appropriate shielding, keeping a distance as safely as possible and reducing radiation time are essential principles for radiation reduction. Eur Heart J 2014; 35: 599–600
- 16 Buchanan GL, Chieffo A, Mehilli J et al. Women In Innovation Group. The occupational effects of interventional cardiology: results from the WIN for Safety survey. EuroIntervention 2012; 8: 658 – 663
- 17 Marinskis G, Bongiorni MG, Dagres N. Scientific Initiative Committee, European Heart Rhythm Association. *et al.* X-ray exposure hazards for physicians performing ablation procedures and device implantation: results of the European Heart Rhythm Association survey. Europace 2013; 15: 444–446
- 18 *Heidbuchel H, Wittkampf FH, Vano E et al.* Practical ways to reduce radiation dose for patients and staff during device implantations and electrophysiological procedures. Europace 2014; 16: 946–964

- 19 *Kuon E, Empen K, Weitmann K et al.* Long-term efficacy of a mini-course in radiation-reducing techniques in invasive cardiology. Fortschritte Röntgenstrahlen 2013; 185: 720 – 725
- 20 Kuon E, Weitmann K, Hoffmann W et al. Multicenter long-term validation of a mini-course in radiation-reducing techniques in the cathlab. Am J Cardiol 2015; 115: 367 – 373 [Epub ahead of print] DOI: 10.1016/ j.amjcard.2014.10.043
- 21 *Kuon E, Weitmann K, Hoffmann W et al.* Efficacy of a mini-course in radiation-reducing techniques in invasive cardiology – a multicenter field study. JACC Cardiovasc Interv 2014; 7: 382–390
- 22 Fetterly KA, Mathew V, Lennon R et al. Radiation dose reduction in the invasive cardiovascular laboratory. Implementing a culture and philosophy of radiation safety. JACC Cardiovasc Interv 2012; 5: 866–873
- 23 *Kuon E.* Radiation exposure in invasive cardiology. Heart 2008; 94: 667-674
- 24 *Kuon E, Weitmann K, Hummel A et al.* Latest-generation catheterization systems enable sub-millisievert invasive coronary angiography. Herz 2013, [Epub ahead of print] 38
- 25 AQUA-Federal evaluation 2012 Coronary angiography and percutaneous coronary intervention (PCI). Indicators of quality. Göttingen: AQUA-Institute for applied quality support and research in health service Ltd [updated 2013 May 30], 62 [German]. Available at: http:// www.sqg.de/downloads/Bundesauswertungen/2012/bu\_Gesamt\_21N3-KORO-PCI\_2012.pdf Accessed 22 December 2014
- 26 Georges JL, Belle L, Ricard C. RAY'ACT investigators. et al. Patient exposure to X-rays during coronary angiography and percutaneous transluminal coronary intervention: Results of a multicenter national survey. Catheter Cardiovasc Interv 2014; 83: 729–738
- 27 *Chambers CE, Fetterly KA, Holzer R et al.* Radiation safety program for the cardiac catheterization laboratory. Catheter Cardiovasc Interv 2011; 77: 546–556
- 28 The International Atomic Energy Agency (IAEA). Radiation protection of patients (RPOP). Available at: http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/

1\_TrainingMaterial/Cardiology.htm Accessed 22 December 2014

- 29 The MARTIR project (Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology). Available at: http://ec.europa.eu/energy/wcm/nuclear/cd\_rom\_martir\_project.zip Accessed 22 December 2014
- 30 Von Bötticher H. CardioPulse. Radiation exposure to personnel in cardiac catheterization laboratories. Eur Heart J 2014; 35: 602
- 31 Azpiri-López JR, Assad-Morell JL, González-González JG et al. Effect of physician training on the X-ray dose delivered during coronary angioplasty. J Invasive Cardiol 2013; 25: 109–113