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

Zusammenfassung


Ergebnisse: Die Kursteilnehmer erzielten signifikante mediane Absenkungen des Dosisflächenprodukts (DPP: von 26,6 auf 13,0 Gy cm²), der Bilderaufnahmen (–29 %), der fluroskopischen DPP/Bild (–32 %), des fluoroskopischen DPP/Sek. (–39 %) und der Durchleuchtungszeit (–16 %). Die Mehrebenen-Analyse ergab niedrigere DPPs mit sinkendem Körpergewichtsindex (–1,4 Gy cm² per kg/m²) und Alter (–1,2 Gy cm²/10 J.), für weibliches Geschlecht (–5,9 Gy cm²), Kursteilnahme der Kardiologen (– 16,1 Gy cm²) und zusätzlich (–9,4 Gy cm²) des Teamleiters, für interventionelle Erfahrung (–0,7 Gy cm²/1000 KA) sowie ältere konventionelle Katheteranlagen (–6,6 Gy cm²). Strahlenschutzmittel wurden in folgender Häufigkeit verwendet: Mantel (100 %), Scheibe (95 %), Untertischlamellen längs/quer (94 %/69 %), Schildrüsen schutz (89 %), Brille (28 %), Patienten-Oberschenkelabdeckung (19 %), Fußschalterabdeckung (7 %), Handschuhe (3 %) und Helm (1 %).


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 Gy cm²), number of radiographic frames (–29 %) and runs (–18 %), fluoroscopic DAP/frame (–32 %), and fluoroscopy time (–16 %). Multilevel analysis revealed lower DAPs with decreasing body mass index (–1.4 Gy cm² per kg/m²), age (–1.2 Gy cm²/decade), female sex (–5.9 Gy cm²), participation of the team leader (–9.4 Gy cm²), the mini-course itself (–16.1 Gy cm²), experience (–0.7 Gy cm²/1000 CAs through the interventionist’s professional life), and use of older catheterization systems (–6.6 Gy cm²). Lead protection included apron (100 %), glass sheet (95 %), lengthwise (94 %) and crosswise (69 %) undercouche 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.

Authors

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Kernaussagen:
- Strahlenschutzmaßnahmen sind in der invasiven Kardiologie unteroptimal umgesetzt.
- Der vorgestellte Strahlenschutz-Minikurs erwies sich als hocheffizient.
- Kardiologen unterschiedlichsten Erfahrungsstandes profitieren 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 resembling radiation [2, 4, 5]. Interventional procedures at more than a few catheterization sites are evidently performed in a manner resembling radiation [2, 4, 5]. Interventional procedures at more than a few catheterization sites are evidently performed in a manner resembling radiation [2, 4, 5]. Interventional procedures at more than a few catheterization sites are evidently performed in a manner resembling radiation [2, 4, 5]. Interventional procedures at more than a few catheterization sites are evidently performed in a manner resembling radiation [2, 4, 5].

Methods

Definitions

The total air kerma is the cumulative dose to the air at the interventional reference point (\(K_R\), 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\(^2\)) is the product of \(K_R\) 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\(^2\) 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 fluoroscopic-guided 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\(^R\)) and fluoroscopic (DAP\(^F\)) fractions, fluoroscopy time, and number of radiographic frames and runs. DAP\(^R\)/frame and DAP\(^F\)/s were calculated as parameters of dose intensity.

The interactive workshop included a standardized oral PowerPoint 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 tech-
nique”; (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 than the esteem accorded to ALARA principles by the International Commission on Radiological Protection 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 interventionists 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 (Fig. 1). The reduction from 26.6 to 13.0 GY × cm$^2$ (− 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 GY × cm$^2$). Operator experience per 1000 CAs performed throughout the interventionalist’s professional life resulted in a lower DAP (− 0.7 GY × cm$^2$), fewer frames and runs and shorter fluoroscopy times (− 11 s). 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

<table>
<thead>
<tr>
<th>n$^1$</th>
<th>median (IQR)</th>
<th>mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>estimated individual values for dose parameters during coronary angiography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dose area product [GY × cm$^2$]</td>
<td>103</td>
<td>25 (16 – 35)</td>
</tr>
<tr>
<td>fluoroscopic fraction [%]</td>
<td>77</td>
<td>30 (20 – 40)</td>
</tr>
<tr>
<td>fluoroscopy time [min]</td>
<td>82</td>
<td>2.5 (2 – 3)</td>
</tr>
<tr>
<td>radiographic frames [n]</td>
<td>60</td>
<td>530 (300 – 700)</td>
</tr>
<tr>
<td>radiographic runs [n]</td>
<td>76</td>
<td>9 (7 – 10)</td>
</tr>
<tr>
<td>length of run [s]</td>
<td>94</td>
<td>3.5 (2.5 – 3.5)</td>
</tr>
<tr>
<td>estimated reduction of radiation exposure [%] due to coronary angiography by optimized...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>collimation to region of interest</td>
<td>92</td>
<td>20 (13 – 30)</td>
</tr>
<tr>
<td>fewer radiographic frames</td>
<td>92</td>
<td>20 (10 – 30)</td>
</tr>
<tr>
<td>lower irradiating angulations</td>
<td>91</td>
<td>15 (10 – 20)</td>
</tr>
<tr>
<td>shorter fluoroscopy times</td>
<td>90</td>
<td>10 (10 – 20)</td>
</tr>
<tr>
<td>estimated value [0...10] attached to ALARA principles by...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>herself/himself</td>
<td>103</td>
<td>8 (6 – 9)</td>
</tr>
<tr>
<td>colleagues</td>
<td>102</td>
<td>7 (5 – 8)</td>
</tr>
<tr>
<td>International Commission on Radiological Protection</td>
<td>92</td>
<td>5 (4 – 9)</td>
</tr>
<tr>
<td>german medical societies</td>
<td>95</td>
<td>5 (3 – 7)</td>
</tr>
</tbody>
</table>

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

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

1 Responses from 115 questionnaires.

2 Antworten in 115 Fragebogen.

3 Range between “no” (0) and “extreme” (10) importance.

Entscheidungsbereich: “keine” (0) … “extreme” (10) Bedeutung.
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

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

<table>
<thead>
<tr>
<th>patients (n = 2260)</th>
<th>operators (n = 113)</th>
<th>centers (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>constant BMI kg/m²</td>
<td>sex</td>
<td>age per decade</td>
</tr>
<tr>
<td>DAP [Gy × cm²]</td>
<td>-13.0</td>
<td>+1.4</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DAP [Gy × cm²]</td>
<td>-4.7</td>
<td>+1.0</td>
</tr>
<tr>
<td>p-value</td>
<td>0.057</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DAP [Gy × cm²]</td>
<td>-5.2</td>
<td>+0.4</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DAP̅F [mGy × cm²]</td>
<td>-14.9</td>
<td>+1.5</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DAP̅j [mGy × cm²]</td>
<td>-13.2</td>
<td>+1.7</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>frames [n]</td>
<td>+718</td>
<td>+1</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>0.345</td>
</tr>
<tr>
<td>runs [n]</td>
<td>+10.0</td>
<td>+0.2</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>0.082</td>
</tr>
<tr>
<td>frames/run [n]</td>
<td>+60.0</td>
<td>-0.1</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001</td>
<td>0.203</td>
</tr>
<tr>
<td>fluoroscopy time [s]</td>
<td>+80.2</td>
<td>+1</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.030</td>
<td>0.116</td>
</tr>
</tbody>
</table>

BMI: per kg/m²; sex = ♀, ♂; operator experience: per 1000 CAs, performed throughout professional life; for all other parameters (mini-course participation, team leader attendance, advanced system): 0 = no, 1 = yes. Projected DAP for CA (BMI 28.0 kg/m², 70 years, ♀), performed by a participant with experience of 200 CAs after the mini-course (participating team leader) with a traditional system: DAP [Gy × cm²] = -13.0 + (28 × 1.4) + (7 × 1.2) + (1 × -16.1) + (0.2 × -0.7) + (1 × -9.4) = 9.0. BMI: body mass index; CA: coronary angiography; DAP̅F/F: radiographic DAP/frame; further abbreviations as in Table 4.

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 4  Ranking of overall course efficacy from best (1) to less than optimal practice (115) after the mini-course (I: black bars) and after the mini-course (II: white bars). Bars indicate performance of each participant before (I: black bars) and after the mini-course (II: white bars).

BMI: per kg/m²; Geschlecht: ♀, ♂; Untersuchererfahrung: ... pro 1000 bislang erbrachte CA; für Kursteilnahme, Teamleiter-Teilnahme, moderne Katheteranlage: 0 = nein, 1 = ja. Kalkuliertes DAP einer CA (BMI 28.0 kg/m², 70 Jahre, ♀), erbracht durch einen Kursteilnehmer mit Erfahrung über 200 CA nach dem Kurs (mit Teilnahme des Teamleiters) an einem konventionellen Katheterrichtung: DAP [Gy × cm²] = -13.0 + (28 × 1.4) + (7 × 1.2) + (1 × -16.1) + (0.2 × -0.7) + (1 × -9.4) = 9.0. BMI: body mass index; CA: coronary angiography; DAP̅F/F: radiografisches DAP/Bild. Weitere Abkürzungen wie in Tab. 4.

Analysis calculated only on the operator level.

Nur auf Untersucherebene kalkulierte Analyse.
27.2 Gy × cm², 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 × cm² ( ● 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 concealed 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-/overcoat 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 Gy × cm² per lifelong-performed 1000 CAs, equivalent to only 3% of the baseline level. This experience parameter reduced the number of radiographic frames, runs and DAP²/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 × cm². 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 interventionists’ 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 toward 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.

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