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Institutional Diagnostic Reference Levels and Peak Skin Doses in selected diagnostic and therapeutic interventional radiology procedures

Emmanouil Papanastasiou [a,*], Athanasios Protopsaltis [a], Stefanos Finitsis [b], Adam Hatzidakis [b], Panos Prassopoulos [b], Anastasios Siountas [a]

[a] Medical Physics Laboratory, School of Medicine, Aristotle University of Thessaloniki, AHEPA University Hospital, Thessaloniki, Greece
[b] Department of Radiology, School of Medicine, Aristotle University of Thessaloniki, AHEPA University Hospital, Thessaloniki, Greece

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ABSTRACT

Purpose: Institutional (local) Diagnostic Reference Levels for Cerebral Angiography (CA), Percutaneous Transhepatic Cholangiography (PTC), Transarterial Chemoembolization (TACE) and Percutaneous Transhepatic Biliary Drainage (PTBD) are reported in this study.
Materials and methods: Data for air kerma-area product (P_{KA}), air kerma at the patient entrance reference point ($K_{a,r}$), fluoroscopy time (FT) and number of images (NI) as well as estimates of Peak Skin Dose (PSD) were collected for 142 patients. Therapeutic procedure complexity was also evaluated, in an attempt to incorporate it into the DRL analysis.
Results: Local P_{KA} DRL values were 70, 34, 189 and 54 Gy.cm^2 for CA, PTC, TACE and PTBD respectively. The corresponding DRL values for $K_{a,r}$ were 494, 194, 1186 and 400 mGy, for FT they were 9.2, 14.2, 27.5 and 22.9 min, for the NI they were 844, 32, 602 and 13 and for PSD they were 254, 256, 1598 and 540 mGy respectively. P_{KA} for medium complexity PTBD procedures was 2.5 times higher than for simple procedures. For TACE, the corresponding ratio was 1.6. PSD was estimated to be roughly 50% of recorded $K_{a,r}$ for procedures in the head/neck region and 10% higher than recorded $K_{a,r}$ for procedures in the body region. In only 5 cases the 2 Gy dose alarm threshold for skin deterministic effects was exceeded.
Conclusion: Procedure complexity can differentiate DRLs in Interventional Radiology procedures. PSD could be deduced with reasonable accuracy from values of $K_{a,r}$ that are reported in every angiography system.

1. Introduction

Over the last three decades, Interventional Radiology (IR) has evolved into an indispensable medical sub-specialty, with an increasing role in diagnosis and therapy of numerous diseases, involving almost every part of the human body. However, since IR procedures are often associated with significant radiation exposures, there is an increased concern about the possible radiation risks to both patients and medical staff. The radiation dose to the patient's skin is of great importance since, on some occasions, the maximum skin dose can exceed the threshold for deterministic effects, namely transient skin erythema, or epilation. Several such unfortunate cases have been reported in the literature [1–3], usually associated with overweight patients [4]. Although some of such cases could be attributed to accidental exposures, most others were almost inevitable due to the long necessary exposure times required to successfully complete complicated procedures, or due to repeated procedures over relatively short periods of time [5].

The concept of Diagnostic Reference Levels (DRL) has been introduced in 1996 [6] by the International Commission on Radiological Protection (ICRP) as an implementation of the ALARA principle. Practical guidance for the establishment and use of DRLs has been issued by the European Commission in 1999 [7] and by ICRP in 2001 [8]. National and European DRLs have been established for many common diagnostic radiology procedures [9–19] and their adoption has contributed significantly to the reduction of the large discrepancy of radiation doses delivered for the same diagnostic examination. A more recent guidance on the implementation of DRLs, including a chapter specially dedicated to IR procedures has been issued by ICRP in 2017 [20]. Since then, it is generally recognized that the degree of complexity of IR procedures may have a stronger effect than patient's weight on the delivered radiation dose, and should therefore be included during data collection for DRL establishment [16].

* Corresponding author at: Medical Physics Laboratory, School of Medicine, Faculty of Health Sciences, Aristotle University of Thessaloniki, Greece.
E-mail address: empapana@auth.gr (E. Papanastasiou).

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FDA regulations [21] require that all fluoroscopic equipment manufactured after 2006 must display at the fluoroscopist's working position the air kerma rate and the cumulative air kerma. The latest European Directive 2013/59/EURATOM [22] requires that "any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures of quantity of radiation produced by the equipment during the procedure". All modern IR angiography systems are equipped with dose monitoring devices which keep track of the procedure's fluoroscopy time (FT), the air kerma ($K_{a,r}$) at the Interventional Reference Point (IRP), the total air kerma-area Product (P_{KA}) and the total Number of Images (NI) recorded (in digital acquisition (DA), digital subtraction angiography (DSA) or cine runs). All these quantities have been proposed as appropriate primary or secondary Diagnostic Reference Quantities for IR procedures [15]. P_{KA} represents the total radiation energy imparted to the patient and therefore relates to their effective dose and the associated subsequent stochastic risk for carcinogenesis. On the other hand, $K_{a,r}$ is usually considered as representative of the maximum dose to the patient's skin and provides an estimate of the patient's risk for developing a radiation injury.

However, $K_{a,r}$ is a crude estimate of patient skin dose because i) the fixed geometrical position of the IRP, which is located 15 cm away from the C-arm's isocenter towards the x-ray tube, does not coincide with the position of patient's skin and ii) the part of the patient's skin that is irradiated during an interventional procedure changes frequently, as a result of the varying C-arm angulations. On the other hand, direct measurement of the patient's skin dose, using either thermoluminescent dosimeters [23,24], optically stimulated luminescence dosimeters [25] or radiochromic films [26,27] attached to the patient's skin, is impractical for everyday clinical use and provides the valuable information of skin dose only after the procedure is completed and the radiation to the patient has already been delivered. This is the reason why many attempts have been made during the last years to develop advanced tools, which combine the traditional radiation dose monitoring information, provided by the system's built-in radiation monitors, with geometrical information of the imaging equipment (C-Arm angulation, patient table position) and size-adjusted patient phantoms, in order to estimate with an increased degree of accuracy the radiation dose to patent's skin [28–33]. Nowadays, such tools have become commercially available and some modern angiographic systems are equipped with sophisticated software, which allow for real-time estimation of the peak skin dose to the patient, thus alerting the interventional radiologist and possibly preventing a possible skin overexposure [34,35].

The main purpose of the present study is to establish Institutional (Local) DRLs for selected diagnostic and therapeutic IR procedures, following the installation of a new angiography system in the Radiology Department of a large University Hospital. A second goal was to explore the effects of procedure complexity in DRLs and to identify significant correlations between the traditional dosimetric quantities usually reported by all angiographic equipment and the Peak Skin Dose provided by the angiography system dedicated software.

2. Materials and methods

Data from 142 patients (79 males – 55.5% and 63 females – 44.4%) who underwent diagnostic or therapeutic interventional radiology procedures at the Radiology Department of AHEPA University Hospital from April 2019 to February 2020, were prospectively collected for this study. Sixty patients, 30 males (50.0%) and 30 females (50.0%), underwent Cerebral Angiography (CA), nineteen patients, 13 males (68.4%) and 6 females (31.6%), underwent Percutaneous Transhepatic Cholangiography (PTC), twenty-five patients, 17 males (68.0%) and 8 females (32.0%), underwent Transarterial Chemoembolization (TACE) and thirty eight patients, 19 males (50.0%) and 19 females (50.0%), underwent Percutaneous Transhepatic Biliary Drainage (PTBD). The age of the patients ranged from 20 to 92 years (mean age: 64.7 years). All procedures were performed by two senior interventional radiologists, each having more than 15 years of experience. During the same period, 64 more patients (41 males – 64.1% and 23 females – 35.9%) had other types of interventional procedures (e.g. extremity angiography or venography, fistulography, adrenal vein sampling, other embolizations) but the number of patients in each type of procedure was<10, which was not considered large enough to be included in the DRL analysis. However, these patients were included in the statistical analysis for the correlation of PSD with the other DRL quantities. Table 1 summarizes some important somatometric patient data for each procedure.

All procedures were performed at a newly installed Canon INFX-8000 V/GC (Infinix-i Biplane) Angiography system (Canon Medical Systems Corp, Japan) equipped with the Dose Tracking System (DTS) for the real-time monitoring of the Peak Skin Dose (PSD) to the patient. This system generates a real-time skin dose map on a 3D height and weight adjusted patient graphic, using information about the C-arms position and angulation, patient table position, field size and entrance skin dose, including backscatter [28]. Before the onset and regularly during the study, a series of quality control measurements were performed at the angiography system, including kV accuracy and reproducibility, beam filtration (HVL), fluoroscopy and acquisition incident air kerma rate, fluoroscopy and acquisition flat panel incident air kerma rate, high contrast and low contrast resolution.

The accuracy of the system's P_{KA} meter which provides the measurements for the dose reports (air kerma at the Interventional Reference Point (IRP) and air kerma-area product) was also verified, using a calibrated Radcal 9015 dosimeter (Radcal Corp, Monrovia, CA) equipped with a 6 cc ionization chamber. The actual P_{KA} value was obtained by measuring the air kerma, K_a, along the central axis of the x-ray beam at a certain distance from the focus and multiplying it by the area, A, of the rectangular x-ray field at the same distance. The field area was determined using the fluoroscopic image of a collimator alignment test tool (Model 161B, Radiation Measurements Inc, Middleton, WI), which was placed perpendicular to the beam axis at the same distance as the ionization chamber. Table attenuation was not included. The actual P_{KA} value was then compared to the value reported by the system. This procedure was repeated for two different kV/additional filtration settings (70 kV/0.6 mmCu and 90 kV/no additional filtration).

A detailed dose report was collected for all patients, as provided by the system, including fluoroscopy and Digital Acquisition (DA) P_{KA}, fluoroscopy and DA $K_{a,r}$, fluoroscopy and DA time, number of images. All these values were reported separately for the Frontal and the Lateral C-arm. The PSD, as provided by the DTS, was also recorded for all patients.

An attempt was made to assess the complexity of each therapeutic IR procedure, calculating a Total Complexity Score (TCS) based on different Complexity Indices (CI) depending on the IR procedure. The CIs used were taken from Ruiz-Cruces et al [12] with minor modifications proposed by our senior interventional radiologists. Tables 2a and 2b list the CIs and the corresponding scoring used for TACE and PTBD respectively. The scoring was assigned by the radiologist who performed each intervention. The TCS for each procedure was calculated by summing each individual CI score. Based on the TCS thus calculated, PTBD procedures were classified, as "simple" (TCS $<$ 10), "medium" (10 $\leq$ TCS $<$ 14) and "complex" (TCS $\geq$ 14). TACE procedures were

Table 1
Number of patients and their somatometric data for each IR procedure.

Type of IR procedure	N	Weight (kg) Mean (SD)	BMI (kg/m^2) Mean (SD)
CA	60	80.5 (15.3)	28.1 (4.5)
PTC	19	72.2 (8.4)	25.5 (2.6)
TACE	25	80.9 (14.9)	27.6 (4.6)
PTBD	38	74.2 (11.0)	25.8 (3.9)
Other	64	77.6 (13.9)	27.1 (5.0)

Table 2a
Complexity Indices (CI) and scoring used for TACE.

CI	Score
#1: related to the anatomical characteristics (tortuosity or angulation of the feeding vessel, atheromatic disease) of the aorta and its branches	1: Low difficulty 2: Medium difficulty 3: High difficulty
#2: related to the configuration of the hepatic arteries or other branches feeding the tumor	1: Standard 2: Feeding arteries in one lobe 3: Feeding arteries in both lobes
#3: related to the type of embolization	1: Lobar unilateral 2: Lobar bilateral or one superselective 3: Two or more superselective
Procedure classification according to Total Complexity Score (TCS):	TCS $<$ 6: Simple 6 $\leq$ TCS $<$ 8: Medium TCS $\geq$ 8: Complex

Table 2b
Complexity Indices (CI) and scoring used for PTBD.

CI	Score
#1: related to the anatomical characteristics	1: Normal liver size 2: Small liver size
#2: related to the degree of intrahepatic biliary ductal dilatation (IBD)	1: IBD very dilated 2: IBD moderately dilated 3: IBD not dilated
#3: related to the location of the obstruction	1: In medial/distal extrahepatic biliary duct 2: In proximal extrahepatic ducts or intrahepatic confluence 3: In multiple IBD
#4: related to passage through the obstruction	1: Easy passage of the obstruction 2: Medium difficulty 3: High difficulty
#5: related to lobes involved	1: Single lobe 2: Both lobes
#6: related to type of biliary drainage	1: External 2: Internal-external 3: Immediate stent placement
Procedure classification according to Total Complexity Score (TCS):	TCS $<$ 10: Simple 10 $\leq$ TCS $<$ 14: Medium TCS $\geq$ 14: Complex

categorized accordingly as “simple” if TCS $<$ 6, “medium” if 6 $\leq$ TCS $<$ 8 and “complex” if TCS $\geq$ 8.

Statistical analysis was performed with the SPSS ver. 25 (IBM Corp. Armonk, NY). Normal distribution of the quantitative parameters was checked with Shapiro-Wilk tests. Mean values, standard deviations (SD), median values and interquartile ranges (IQR) were appropriately calculated for continuous variables. Mann-Whitney tests and Wilcoxon Signed Rank tests were appropriately used to compare median DRL quantities between groups of patients and other dosimetric characteristics in each procedure. Spearman correlations were appropriately used to identify significant correlations between quantitative variables. Statistical significance was accepted for $p < 0.05$.

3. Results

The detailed dose measurements with the calibrated dosimeter verified the accuracy of the values of P_{KA} and $K_{a,r}$ provided by the system to within<10%. This is well below the acceptance limits that usually apply for such measurements (±35% for P_{KA} and ± 20% for $K_{a,r}$). Since the estimated overall uncertainties of our own P_{KA} measurements were of the same order of magnitude (±3% uncertainty in dose measurements, ±2% in the field area and ± 1% in focus-to-dosimeter distance), it was decided not to correct the system reported values.

Both C-arms of the biplane system (frontal and lateral) were used during all CA procedures. On average, the frontal plane accounted for 80% of the total P_{KA} (median 82%, range 42–91%) and for 85% of the total $K_{a,r}$ (median 87%, range 56–96%). On average, 24% of the total P_{KA} (median 18%, range 7–89%) and 18% of the total $K_{a,r}$ (median 12%, range 5–78%) was due to fluoroscopy. On the other hand, all PTC, TACE and PTBD procedures were performed using the frontal C-arm only.

The contribution of fluoroscopy and DA was not the same for all types of procedures (Fig. 1). Limited use of DA was generally observed in PTC and PTBD. In PTC, on average, 85% of the total P_{KA} (median 99%, range 21–100%) and 87% of the total $K_{a,r}$ (median 99%, range 31–100%) was due to fluoroscopy. In PTBD, the corresponding values were 94% for P_{KA} (median 99%, range 8–100%) and 92% for $K_{a,r}$ (median 95%, range 14–100%). On the other hand, DA contributed significantly more to the total dose than fluoroscopy in CA (Wilcoxon Signed Rank test, $p < 0.001$). On average, 81% of the total P_{KA} (median 86%, range 20–94%) and 82% of the total $K_{a,r}$ (median 88%, range 12–95%) was due to DA. In TACE, the differences in the contribution of fluoroscopy and DA to the total dose were statistically significant for P_{KA}, but not for $K_{a,r}$ (Wilcoxon Signed Rank test, $p = 0.007$ and $p = 0.201$ respectively). On average, 60% of the total P_{KA} (median 61%, range 17–81%) and 53% of the total $K_{a,r}$ (median 53%, range 20–82%) was due to DA.

Tables 3, 4, 5 and 6 present descriptive statistics for the DRL quantities (mean values, standard deviations, median values and interquartile ranges) and the corresponding local DRL values (75% percentile) for CA, PTC, TACE and PTBD procedures respectively. Fig. 2 presents (in the form of box plots) the distributions of each of the DRL quantities (P_{KA}, $K_{a,r}$, fluoroscopy time, number of images and peak skin dose) for CA, PTC, TACE and PTBD procedures.

Based on the calculated TCS, TACE and PTBD procedures were appropriately characterized as “simple”, “medium” or “complex”. In PTBD, 20 procedures (53%) were characterized as “simple” and the remaining 18 (47%) as “medium”. In TACE, 18 procedures (72%) were characterized as “simple” and the remaining 7 (28%) as “medium”. No procedure was identified as “complex”. Separate distributions of the DRL quantities for TACE and PTBD, according to procedure complexity, are given in Fig. 3.

Table 7 lists the Spearman correlation coefficients of PSD with all the DRL quantities, for each type of procedure. This analysis includes also data from the 64 patients who underwent other types of IR procedures. $K_{a,r}$ and PSD data from all 206 patients were separated into two groups, according to whether the procedure involved the head/neck or the body region. Fig. 4a and 4b present scatter plots of PSD vs $K_{a,r}$ separately for these groups, along with the corresponding linear and power regression fit lines.

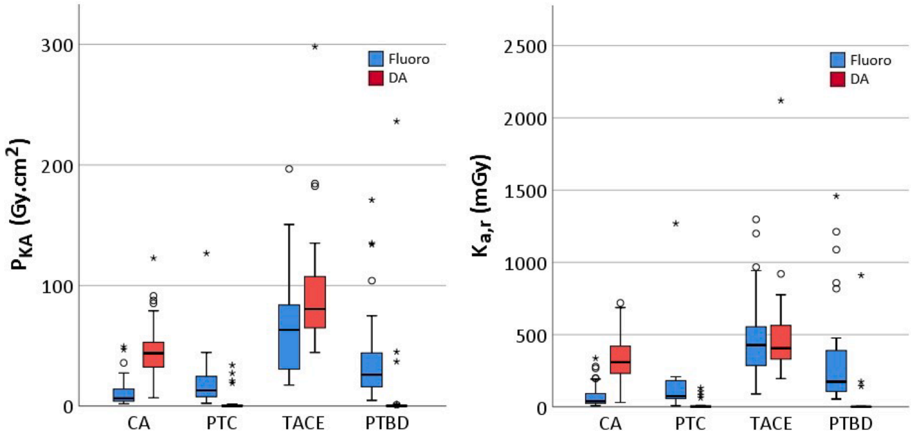

Fig. 1. Box plots of the contribution of fluoroscopy and DA into P_{KA} and $K_{a,r}$ for CA, PTC, TACE and PTBD procedures.

Table 3
Descriptive statistics and Local DRL values for CA.

DRL quantity	Mean (SD)	Median (IRQ)	75th percentile
P_{KA} (Gy.cm^2)	55.5 (26.1)	50.4 (30.7)	70.2
$K_{a,r}$ @ IRP (mGy)	400.6 (188.8)	367.5 (227.0)	494.0
Fluroroscopy time (min)	7.4 (6.1)	5.2 (5.6)	9.2
No of images	624 (294)	628 (447)	844
Peak Skin Dose (mGy)	180 (111)	157 (159)	254

Table 4
Descriptive statistics and Local DRL[†] values for PTC.

DRL quantity	Mean (SD)	Median (IRQ)	75th percentile
P_{KA} (Gy.cm^2)	27.8 (30.1)	17.4 (25.3)	34.4
$K_{a,r}$ @ IRP (mGy)	182.5 (275.2)	108.3 (124.5)	194.0
Fluroroscopy time (min)	10.8 (9.5)	8.7 (10.9)	14.2
No of images	60 (123)	3 (31)	32
Peak Skin Dose (mGy)	241 (332)	136 (169)	256

[†] Due to the limited number of patients, these values should be considered as indicative.

Table 5
Descriptive statistics and Local DRL values for TACE.

DRL quantity	Mean (SD)	Median (IRQ)	75th percentile
P_{KA} (Gy.cm^2)	163.8 (82.4)	154.0 (87.7)	189.2
$K_{a,r}$ @ IRP (mGy)	999.7 (618.2)	870.0 (607.7)	1185.5
Fluroroscopy time (min)	22.1 (9.8)	19.6 (12.4)	27.5
No of images	427 (316)	319 (414)	602
Peak Skin Dose (mGy)	1229 (604)	1103 (799)	1598

Table 6
Descriptive statistics and Local DRL[†] values for PTBD.

DRL quantity	Mean (SD)	Median (IRQ)	75th percentile
P_{KA} (Gy.cm^2)	48.6 (54.5)	31.9 (38.1)	53.8
$K_{a,r}$ @ IRP (mGy)	353.4 (367.1)	253.3 (292.4)	399.8
Fluroroscopy time (min)	16.6 (10.4)	13.3 (13.5)	22.9
No of images	55 (175)	8 (8)	13
Peak Skin Dose (mGy)	411 (445)	262 (414)	540

[†] Due to the limited number of patients, these values should be considered as indicative.

4. Discussion

Since their introduction, DRLs have contributed significantly to the goal of optimization of radiation doses required for typical diagnostic radiology procedures. During the last few years, their use has been extended also to IR procedures. National DRLs for IR procedures have not been established yet in our country. Local (institutional) DRLs for four common diagnostic and therapeutic IR procedures are presented in this study. The four DRL quantities, recommended by the latest international recommendations, were collected for analysis, supplemented by the estimated patient's peak skin dose as provided by the DTS installed in the angiography system.

Among the four procedures, TACE was the one that delivered the highest doses to patients and required the highest fluoroscopy times. Table 8 summarizes and compares DRL values derived in this study, with national or local DRLs, or other values reported in the literature [36–47], including the recently published final report of the EUCLID European project [16], which proposed European DRLs for TACE and PTBD (among others). P_{KA} and $K_{a,r}$ values from our study are generally lower. Increased values, compared to the literature, are sometimes observed in fluoroscopy time and in the number of images. The observation of elevated fluoroscopy times which, on the other hand, result in lower doses may be explained by the systematic use of low pulse-rate fluoroscopy in our study. A possible explanation for the elevated number of images could be the inconsistency in the interpretation of this specific parameter among different hospitals (due to the use of either fluoroscopy or radiography to archive and document their procedures). This was the reason why, in the EUCLID report, it was proposed that this parameter should be excluded from DRL analysis [16].

The comparison between current patient doses and the corresponding values that were obtained three years ago, at the same institution when the older angiographic system was still in use, revealed that the current patient doses for CA are almost 60% lower (new mean P_{KA} of 55.5 Gy.cm^2 compared to old mean P_{KA} of 134.6 Gy.cm^2, new mean $K_{a,r}$ of 400.6 mGy compared to old mean $K_{a,r}$ of 1064 mGy and new mean FT of 7.4 min compared to old mean FT of 12.4 min) and for PTC are more than 70% lower (new mean P_{KA} of 27.8 Gy.cm^2 compared to old mean P_{KA} of 88.6 Gy.cm^2, new mean $K_{a,r}$ of 182.5 mGy compared to old mean $K_{a,r}$ of 1035 mGy and new mean FT of 10.8 min compared to old mean FT of 37.4 min).

Statistically significant correlations were found between almost all DRL quantities for all procedure types. P_{KA} correlated very strongly with $K_{a,r}$, (Spearman's rho 0.928 ($p < 0.001$) for CA, 0.898 ($p < 0.001$) for PTC, 0.938 ($p < 0.001$) for PTBD and 0.857 ($p < 0.001$) for TACE) and less strongly, but always significantly, with fluoroscopy time and number of images. As expected, no significant correlations were observed between fluoroscopy time and number of images, since these parameters refer to different modes of x-ray tube operation.

Statistically significant differences in DRL quantities between male and female patients were generally not observed (Mann-Whitney test). Only P_{KA} in CA ($p = 0.04$) and fluoroscopy time in TACE ($p = 0.006$)

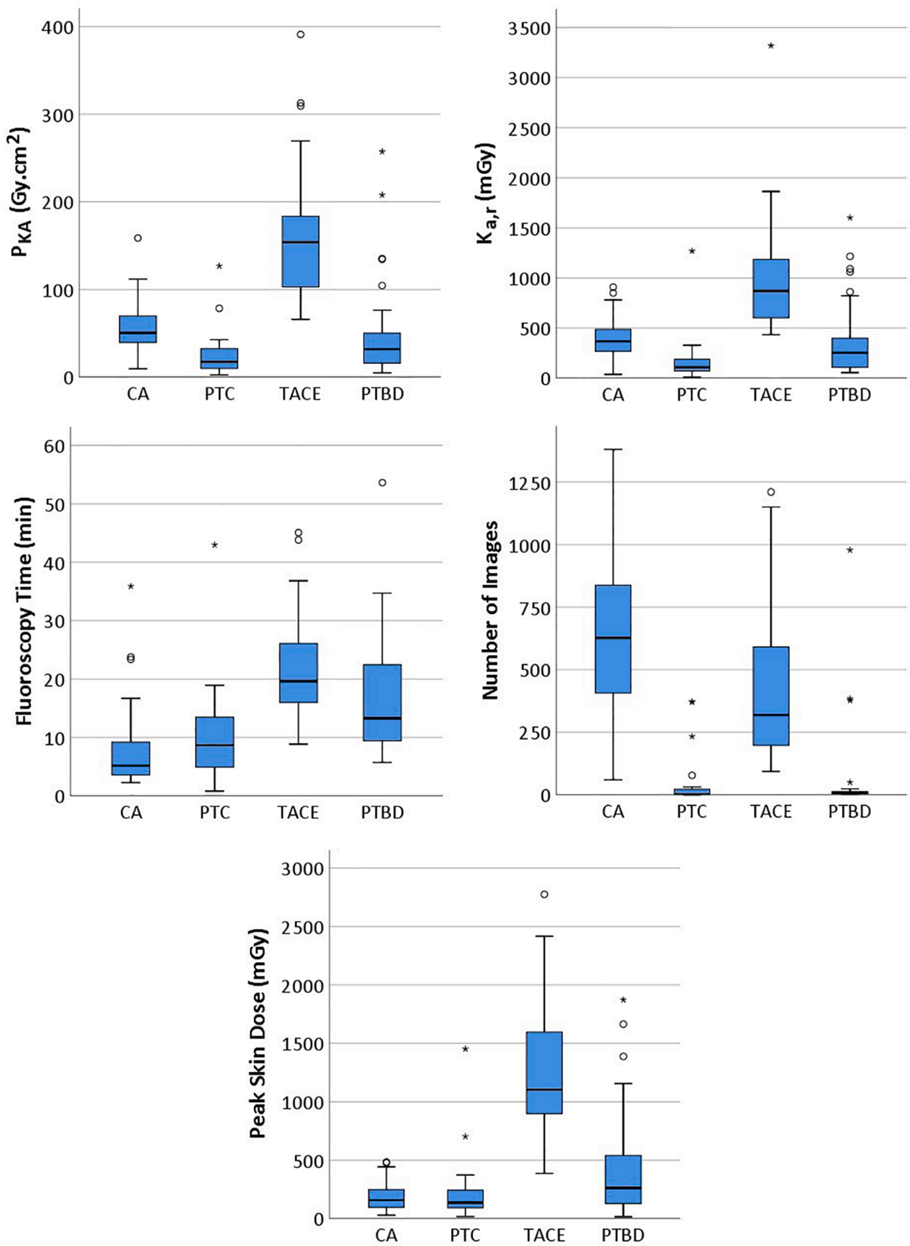

Fig. 2. Box plots of the distribution of the DRL quantities for CA, PTC, TACE and PTBD procedures.

were found to be statistically different. Some statistically significant differences were observed between groups of patients with different somatometric characteristics. For each type of procedure, Body Mass Index and Body Surface Area were calculated for all patients. Patients were subsequently divided into two groups, with respect to the corresponding median BMI and BSA values. Comparisons were then made for all DRL quantities, between these groups. Statistically significant differences between BMI groups were observed in fluoroscopy time ($p = 0.009$) for PTC, number of images ($p = 0.033$) for PTBD and in P_{KA} ($p = 0.001$), $K_{a,r}$ ($p = 0.005$) and PSD ($p = 0.001$) for TACE. Statistically significant differences between BSA groups were observed in P_{KA} ($p = 0.027$) and fluoroscopy time ($p = 0.028$) for CA and PSD ($p = 0.046$) for TACE. These results support the fact that in IR procedures, as opposed to the classic radiological examinations, patient size is not the primary determinant of patient dose.

The effect of procedure complexity on patient doses in interventional cardiology has been examined in the literature [48–50]. Similar effects are anticipated in IR procedures too. The introduction of procedure complexity into the concept of DRLs has led to attempts to describe complexity in a semi-quantitative manner, in order to classify procedures in a three-point scale (simple, medium or complex) and produce separate DRL values for each complexity category [12]. The results of the present study show that, at least for PTBD, procedure complexity plays an important role in patient dose. All DRL quantities except the number of images were found to be statistically different between "simple" and "medium" procedures in PTBD (Mann-Whitney test, $K_{a,r}$: $p < 0.001$, P_{KA}: $p = 0.002$, fluoroscopy time: $p = 0.001$, PSD: $p = 0.001$, number of images: $p = 0.067$). The ratio of the mean value of P_{KA} between simple and medium procedures was found to be equal to 2.5. In the study of Ruiz-Cruces et al [12] the corresponding ratio between the proposed DRLs was equal to 3.0. On the other hand, for TACE, only $K_{a,r}$ was found to be statistically different between "simple" and "medium" procedures (Mann-Whitney test, $K_{a,r}$: $p = 0.034$, P_{KA}: $p = 0.141$, fluoroscopy time: $p = 0.110$, number of images: $p = 0.574$, PSD: $p = 0.064$). It is believed, though, that this result could be due to the small number of patients in the "medium" complexity TACE group (only 7) that has

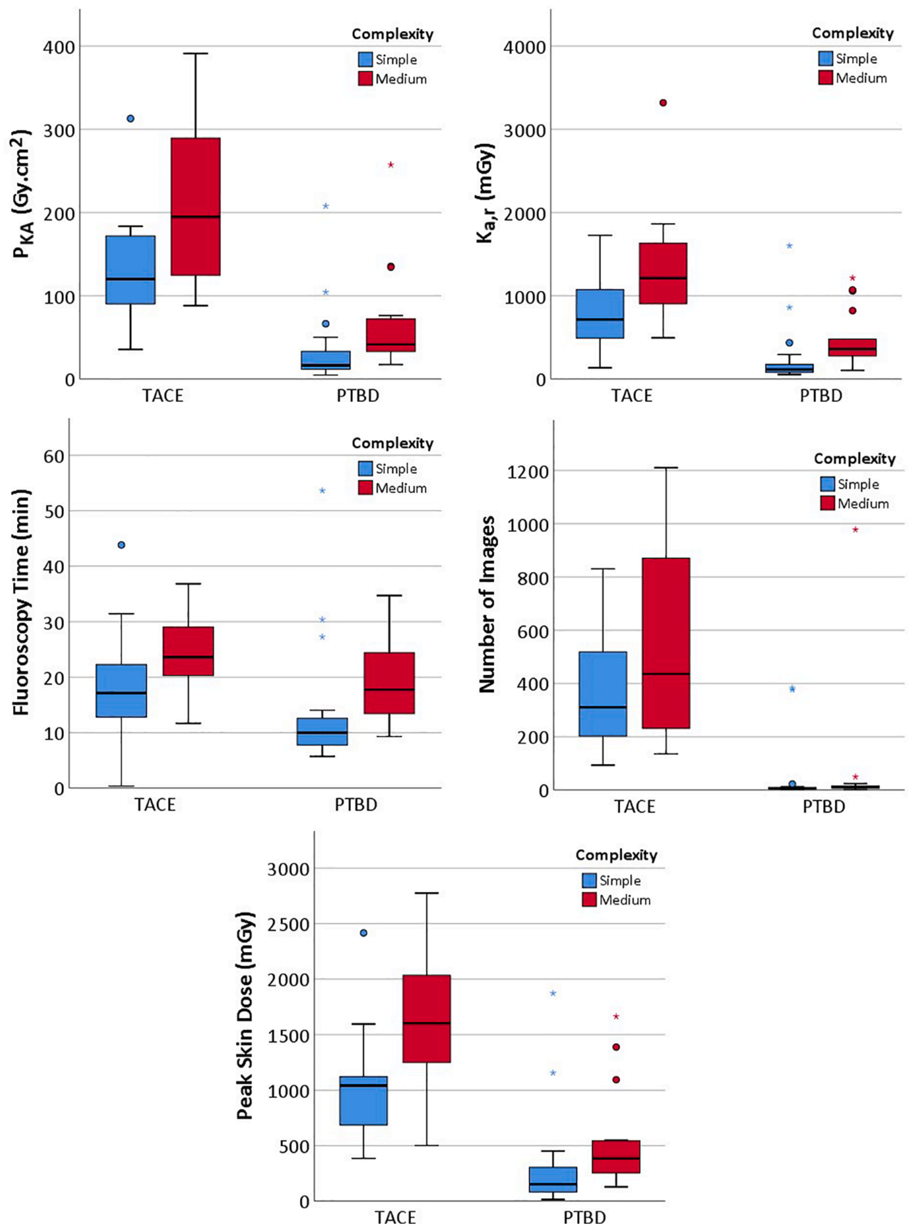

Fig. 3. Box plots showing differences in the distribution of the DRL quantities between simple and medium complexity therapeutic procedures.

Table 7
Spearman correlation coefficients between PSD and each of the DRL quantities for each procedure.

Type of IR procedure	Spearman's rho (p value) $K_{a,r}$	P_{KA}	FT	No of images
CA	0.661 (<0.001)	0.646 (<0.001)	0.461 (<0.001)	0.418 (0.001)
PTC	0.904 (<0.001)	0.881 (<0.001)	0.695 (0.001)	0.517 (0.023)
TACE	0.922 (<0.001)	0.884 (<0.001)	0.759 (<0.001)	0.397 (0.049)
PTBD	0.961 (<0.001)	0.910 (<0.001)	0.654 (<0.001)	0.576 (<0.001)
Other	0.965 (<0.001)	0.954 (<0.001)	0.797 (<0.001)	0.725 (<0.001)

compromised the statistical power of the study. The ratio of the mean value of P_{KA} between simple and medium procedures was found to be equal to 1.6. In the study of Ruiz-Cruces et al [12] the corresponding ratio between the proposed DRLs was equal to 1.8, which is very similar.

PSDs were generally lower than the 2 Gy dose alarm threshold that is usually set for IR procedures. The threshold was exceeded in 5 cases: 3 TACE (1 simple and 2 of medium complexity) and 2 procedures belonging to the "other" group. The 3 Gy dose threshold, that must be recorded in the patient's record, as recommended by ICRP [51], was slightly exceeded in only one case (PSD: 3.15 Gy).

$K_{a,r}$ was the DRL quantity that showed the highest correlation with PSD (Table 7), followed by P_{KA}. Plotting PSD versus $K_{a,r}$ for each type of procedure, formed two quite distinct clusters, one for CA and "other" procedures involving the head/neck region and the second for PTC,

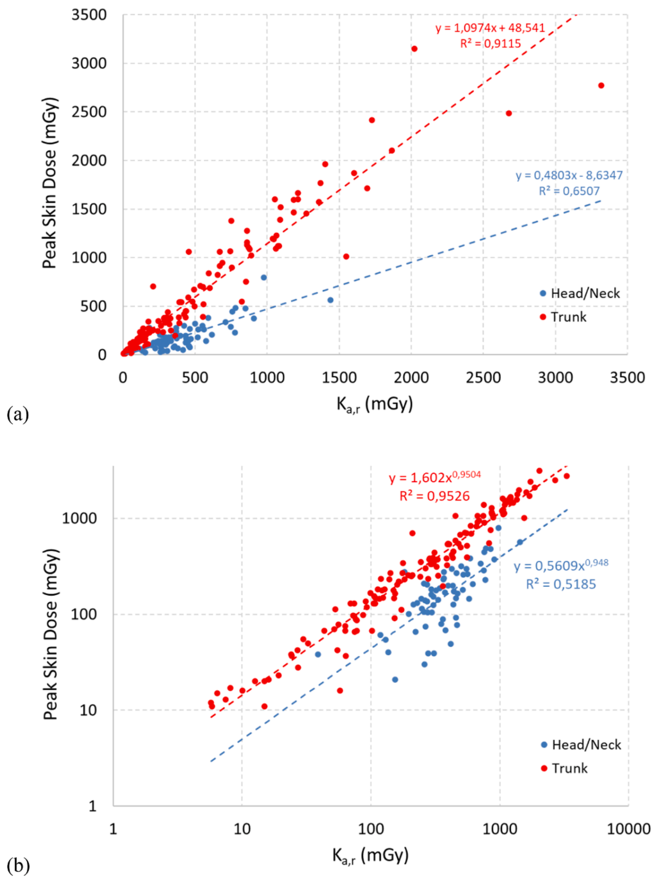

Fig. 4. PSD as a function of $K_{a,r}$, for IR procedures at the head/neck or trunk region. (a): linear fitting, (b) power fitting (note: log scale in both axes).

TACE, PTBD and “other” procedures involving the trunk. Linear regression gave two equations (Fig. 4a) with different slopes, a slope of 0.48 for the first cluster (R^2: 0.65) and of 1.1 for the second (R^2: 0.91). A power fitting (equivalent to a linear fitting after logarithmic transformation of $K_{a,r}$ and PSD [52]) resulted in a lower R^2 of 0.52 for the head/neck cluster, but a higher R^2 of 0.95 for the trunk cluster (Fig. 4b). Calculation of the residuals for both fittings revealed that the power fitting provided more accurate PSD predictions from $K_{a,r}$, especially in the very low dose region (below 100 mGy) for procedures involving the trunk: using the linear fitting, PSD was predicted within ± 35% in only 6% of the cases, compared to 74% of the cases using the power fitting. For doses higher than 100 mGy, the differences between the two fittings became insignificant for both head/neck and trunk procedures: in the 100–200 mGy dose region (46 cases), the linear fitting predicted PSD within ± 35% in 87% of the cases, whereas the power fitting in 89%. The corresponding values for the 200–500 mGy dose region (54 cases) were 80% (linear) versus 72% (power) and for doses higher than 500 mGy (56 cases) the values were the same (89%) for both fittings. Considering the simplicity of the linear model and the fact that accurate PSD predictions are more important for doses higher than 200 mGy, we conclude that it is preferable to use the linear equations, which can be simplified as follows: for procedures involving the head/neck region, one can roughly estimate patient’s PSD by dividing recorded $K_{a,r}$ by a factor of 2; for procedures involving the trunk region, $K_{a,r}$ underestimates PSD by roughly 10%. Although methods for more accurate predictions of PSD from $K_{a,r}$ or P_{KA} have been proposed in the literature [52,53] the above can be a helpful “rule of thumb” for the interventional radiologists.

The implementation of the DRL concept is an ongoing continuous process of data collection, processing and analysis, which can lead to updates and revisions of the DRL values. The establishment of local DRLs for other common IR procedures in our hospital and the update of the current study reported values, especially for PTC and TACE which are based in a relatively smaller number of patients, is currently under way. It is also hoped that the reported DRL values will increase the awareness of our trainee and relatively inexperienced interventional radiologists in radiation protection and will provide a means of testing their own practice. An investigation of the performance of the angiography system and/or individual practices will be performed if the local DRL values are systematically exceeded. Data reported in this study could also contribute to the establishment of national DRLs for common IR procedures.

Table 8
Comparison of DRL quantities from this study with other studies.

		P_{KA} (Gy. cm^2)	$K_{a,r}$ (mGy)	FT (min)	No of images
CA	This study	70.2	494	9.2	844
	McParland [36]	82.5			
	Brambilla [37]	198			
	Aroua [38]	125		15	480
	Bleeser [39]	75			
	Vano [40]	107		12	550
	Etard [13]	87.5	628	10.3	389
	Rizk [41]	83	690	6	385
PTC	This study	34.4	194	14.2	32
	McParland [36]	107		16.6	
	Brambilla [37]	62–158†			
	Tsalafoutas [42]	1.3–75.7†	4–1036†	0.3–23.4†	
TACE	This study	189.2	1185.5	27.5	602
	Vano [43]	289		24.3	182
	Miller [44]	400	1900	25	300
	Ruiz-Cruces [12]	303		26.3	245
	Etard [13]	249.2	987	27.1	197
	Rizk [41]	522	2890	29	314
	Lee [45]	237.7		20.4	
	EUCLID [16]	241	1867	18	
PTBD	This study	53.8	399.8	22.9	13
	Stratakis [46]	25.5§		11.5§	
	Aroua [38]	240		25	30
	Vano [43]	80		19.8	27
	Miller [44]	100	1400	30	20
	Ruiz-Cruces [12]	30		17.3	7
	Heillmeier [47]	60.5			
	Etard [13]	33.5	253	15.7	8
	Rizk [41]	148	990	20	67
	Lee [45]	37.5		7.1	
	EUCLID [16]	22	194	10	

† ranges, or §averages instead of 3rd quartile values were reported.

4.1. Limitations

A first limitation of this study is the relatively small number of patients enrolled, which did not allow us to derive institutional DRLs for more types of IR procedures. Furthermore, dividing patients into complexity categories has reduced further the number of patients in each category, weakening the strength of the corresponding statistical comparisons. The reason why data collection ended prematurely was the onset of the COVID-19 pandemic, which totally disrupted the patient flow in our IR department. A second limitation is that our study does not include a separate analysis of the doses delivered to the patients by Cone Beam CT acquisitions, because the corresponding data were not included as separate entries in the system dose reports. In our institution, CBCT acquisitions are routinely performed only for CA procedures (1–4 acquisitions per patient, usually 3) and the data for CBCT doses are incorporated into the DA P_{KA}, DA $K_{a,r}$, DA time and NI values of the system dose reports. Although we did not have the data to calculate the contribution of CBCT acquisitions for each specific patient, experiments with a head phantom showed that P_{KA} from a typical CBCT DSA (20 cm FOV) acquisition was of the order of 9 Gy.cm^2 and $K_{a,r}$ was of the order of 80 mGy. For a typical CBCT DA (20 cm FOV) acquisition, the corresponding values were 1.5 Gy.cm^2 and 13 mGy. Finally, a third limitation is that the accuracy of the peak skin doses reported by the system's DTS was not verified using another independent method (radiochromic film, or TLDs). It was accepted that this accuracy is better than ± 10%, as reported in the literature [54].

5. Conclusions

Institutional DRLs were established for four IR procedures (CA, PTC, TACE and PRBD). DRLs for the dosimetric quantities (P_{KA} and $K_{a,r}$) were found to be lower than other national and international published values. Procedure complexity was found to affect patient doses, at least for PTBD. Peak skin doses, provided by the angiography system's dedicated software, were generally below the alarm threshold for skin deterministic effects of 2 Gy. The threshold was exceeded in only 5 out of 206 cases. PSD correlated strongly with $K_{a,r}$. For procedures involving the head/neck region, PSD were found to be roughly equal to 50% of the recorded $K_{a,r}$. For procedures in the body region, PSD were roughly 10% higher than the recorded $K_{a,r}$.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

[1] Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. Radiology 2010;254(2):326–41. https://doi.org/10.1148/radiol.2542082312.
[2] Shope TB. Radiation-induced Skin Injuries from Fluoroscopy. Radiographics 1996; 16(5):1195–9. https://doi.org/10.1148/radiographics.16.5.8888398.
[3] International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP publication 85, Oxford, Elsevier; 2000.
[4] Sánchez RM, Vañó E, García LE, Fernández JM. Reducing the risk of skin injuries in cardiac catheterization procedures: Optimization proposal for obese patients. Phys Med 2018;53:94–102. https://doi.org/10.1016/j.ejmp.2018.08.012.
[5] Vano E, Goicolea J, Galvan C, Gonzalez L, Meiggs L, Ten JI, et al. Skin radiation injuries in patients following repeated coronary angioplasty procedures. Br J Radiol 2001;74(887):1023–31. https://doi.org/10.1259/bjr.74.887.741023.
[6] International Commission on Radiological Protection. Radiological Protection and Safety in Medicine. ICRP Publication 73, Oxford, Elsevier; 1996.
[7] European Commission. Guidance on Diagnostic Reference Levels (DRLs) for Medical Exposures. Radiation Protection 109, Directorate-General; 1999.
[8] International Commission on Radiological Protection. Radiation and your patient: A guide for medical practitioners: ICRP Supporting Guidance 2: Approved by ICRP Committee 3 in September 2001. Oxford: Elsevier; 2002.
[9] HPA-CRCE-034: Doses to patients from radiographic and fluoroscopic x-ray imaging procedures in the UK-2010 review. London, Health Protection Agency; 2012.
[10] National Council on Radiation Protection & Measurements. Reference levels and achievable doses in medical and dental imaging: recommendations for the United States. NCRP Report 172, Bethesda; 2012.
[11] Simantirakis G, Hourdakis CJ, Economides S, Kaisas I, Kalathaki M, Koukorava C, et al. Diagnostic reference levels and patient doses in computed tomography examinations in Greece. Rad Prot Dosim 2015;163(3):319–24. https://doi.org/10.1093/rpd/ncu182.
[12] Ruiz-Cruces R, Vano E, Carrera-Magariño F, Moreno-Rodriguez F, Soler-Cantos MM, Canis-Lopez M, et al. Diagnostic reference levels and complexity indices in interventional radiology: a national programme. Eur Radiol 2016;26 (12):4268–76. https://doi.org/10.1007/s00330-016-4334-2.
[13] Etard C, Bigand E, Salvat C, Vidal V, Beregi JP, Hornbeck A, et al. Patient dose in interventional radiology: a multicentre study of the most frequent procedures in France. Eur Radiol 2017;27(10):4281–90. https://doi.org/10.1007/s00330-017-4780-5.
[14] Schegerer A, Loose R, Heuser LJ, Brix G. Diagnostic Reference Levels for Diagnostic and Interventional X-Ray Procedures in Germany: Update and Handling. Fortschr Röntgenstr (RöFo) 2019;191(08):739–51. https://doi.org/10.1055/a-0824-7603.
[15] European Commission. Diagnostic Reference Levels in Thirty-six European Countries. Radiation Protection 180, Part 2/2. Directorate-General; 2014.
[16] European Commission. European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging. Radiation Protection 195, Directorate-General; 2021.
[17] Aberle C, Ryckx N, Treier R, Schindera S. Update of national diagnostic reference levels for adult CT in Switzerland and assessment of radiation dose reduction since 2010. Eur Radiol. 2020;30(3):1690–700. https://doi.org/10.1007/s00330-019-06485-1.
[18] Wachabauer D, Röthlin F, Moshammer HM, Homolka P. Diagnostic Reference Levels for computed tomography in Austria: A 2018 nationwide survey on adult patients. Eur J Radiol 2020;125:108863. https://doi.org/10.1016/j.ejrad.2020.108863.
[19] Wachabauer D, Röthlin F, Moshammer HM, Homolka P. Diagnostic Diagnostic Reference Levels for conventional radiography and fluoroscopy in Austria: Results and updated National Diagnostic Reference Levels derived from a nationwide survey. Eur J Radiol 2019;113:135–9. https://doi.org/10.1016/j.ejrad.2019.02.015.
[20] International Commission on Radiological Protection. Diagnostic Reference Levels in Medical Imaging. ICRP Publication 135, Sage; 2017.
[21] US Food and Drug Administration. Performance Standards for Ionizing Radiation Emitting Products, 21CFR1020.32; 2013.
[22] European Council Directive 2013/59/Euratom on basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. OJ of the EU. L13; 57: 1–73; 2014.
[23] Delichas MG. Psarrakos K, Giannoglou G, Molyvda-Athanasopoulou E, Hatziioannou, K et al. Skin doses to patients undergoing Coronary Angiography in a Greek Hospital. Rad Prot Dosim 2005; 113(4): 449-52. Doi: 10.1093/rpd/nch486.
[24] Farah J, Trianni A, Carinou E, Ciraj-Bjelac O, Clairand I, Dabin J, et al. Measurement of maximum skin dose in interventional radiology and cardiology and challenges in the set-up of European alert thresholds. Rad Prot Dosim 2015; 164(1-2):138–42. https://doi.org/10.1093/rpd/ncu314.
[25] Balaguru D, Rodriguez M, Leon S, Wagner LouisK, Beasley CharlesW, Sultzer A, et al. Comparison of skin dose measurement using nanoDot® dosimeter and machine readings of radiation dose during cardiac catheterization in children. Ann Pediatr Cardiol 2018;11(1):12. https://doi.org/10.4103/apc.APC_86_17.
[26] Greffier J, Goupil J, Larbi A, Stefanovic X, Pereira F, Moliner G, et al. Assessment of patient's peak skin dose during abdominopelvic embolization using radiochromic (Gafchromic) films. Diagn Interv Imaging 2018;99(5):321–9. https://doi.org/10.1016/j.diii.2017.12.008.
[27] Pasquino M, Cutaia C, Poli M, Valero C, Peroni G, De Benedictis M, et al. Patient's Peak Skin Dose evaluation using Gafchromic films in interventional cardiology procedures and its correlation with other dose indicators. Phys Med 2018;53:103–7. https://doi.org/10.1016/j.ejmp.2018.08.017.
[28] Rana VK, Rudin S, Bednarek DR. A tracking system to calculate patient skin dose in real-time during neurointerventional procedures using a biplane x-ray imaging system. Med Phys 2016;43(9):5131–44. https://doi.org/10.1118/1.4960368.
[29] Greffier J, Van Ngoc Ty C, Bonniaud G, Moliner G, Ledermann B, Schmutz L, et al. Assessment of peak skin dose in interventional cardiology: A comparison between Gafchromic film and dosimetric software em.dose. Phys Med 2017;38:16–22. https://doi.org/10.1016/j.ejmp.2017.05.044.
[30] Habib Geryes B, Hadid-Beurrier L, Waryn M-J, Jean-Pierre A, Farah J. Benchmarking the DACS-integrated Radiation Dose Monitor® skin dose mapping software using XR-RV3 Gafchromic® films. Med Phys 2018;45(10):4683–92. https://doi.org/10.1002/mp.2018.45.issue-1010.1002/mp.13125.
[31] Didier R, Bourhis D, Oueslati C, Nasr B, Le Ven F, Noël A, et al. In vivo validation of Dosemap software use in interventional cardiology with dosimetrics indicators and peak skin dose evaluation. Catheter Cardiovasc Interv 2019;94(2):216–22. https://doi.org/10.1002/ccd.v94.210.1002/ccd.28097.
[32] Colombo PE, Rottoli F, Felisi M, De Mattia C, Riga S, Sutto M, et al. Validation of a dose tracking software for skin dose map calculation in interventional radiology. Phys Med 2020;72:122–32. https://doi.org/10.1016/j.ejmp.2020.03.008.
[33] Krajinović M, Kržanović N, Ciraj-Bjelac O. Vendor-independent skin dose mapping application for interventional radiology and cardiology. J App Clin Med Phys 2021; 22(2):145–57. https://doi.org/10.1002/acm2.v22.210.1002/acm2.13167.
[34] Jarvinen H, Farah J, Siiskonen T, Ciraj-Bjelac O, Dabin J, Carinou E, et al. Feasibility of setting up generic alert levels for maximum skin dose in fluoroscopically guided procedures. Phys Med 2018;46:67–74. https://doi.org/10.1016/j.ejmp.2018.01.010.
[35] Sas N, Magnier F, Pouget E, Dedieu V, Guersen J, et al. Optimized radiological alert thresholds based on device dosimetric information and peak skin dose in vascular fluoroscopically guided intervention. Eur Radiol 2020; online ahead of print. Doi: 10.1007/s00330-020-07422-3.
[36] McParland BJ. A study of patient radiation doses in interventional radiological procedures. Br J Radiol 1998;71(842):175–85. https://doi.org/10.1259/bjr.71.842.9579182.
[37] Brambilla M, Marano G, Dominietto M, Cotroneo AR, Carriero A. Patient radiation doses and references levels in interventional radiology [Dose al paziente e livelli di riferimento in radiologia interventistica]. Radiol Med 2004;107(4):408–18.

[38] Aroua A, Rickli H, Stauffer J-C, Schnyder P, Trueb PR, Valley J-F, et al. How to set up and apply reference levels in fluoroscopy at a national level. Eur Radiol 2007;17(6):1621–33. https://doi.org/10.1007/s00330-006-0463-3.

[39] Bleeser F, Hoornaert M-T, Smans K, Struelens L, Buls N, Berus D, et al. Diagnostic reference levels in angiography and interventional radiology: a Belgian multi-centre study. Rad Prot Dosim 2008;129(1-3):50–5. https://doi.org/10.1093/rpd/ncn028.

[40] Vano E, Jarvinen H, Kosunen A, Bly R, Malone J, Dowling A, et al. Patient dose in interventional radiology: A European survey. Rad Prot Dosim 2008;129(1-3):39–45. https://doi.org/10.1093/rpd/ncn024.

[41] Rizk C, Farah J, Vanhavere F, Fares G. National diagnostic reference levels in interventional radiology suites in Lebanon: a multicenter survey. Rad Prot Dosim 2019;187(1):50–60. https://doi.org/10.1093/rpd/ncz137.

[42] Tsalafoutas IA, Goni H, Maniatis PN, Pappas P, Bouzas N, Tzortzis G. Patient doses from noncardiac diagnostic and therapeutic interventional procedures. J Vasc Interv Radiol 2006;17(9):1489–98. https://doi.org/10.1097/01.RVI.0000233526.17393.E4.

[43] Vano E, Sanchez R, Fernandez JM, Gallego JJ, Verdu JF, de Garay MG, et al. Patient dose reference levels for interventional radiology: A national approach. Cardiovasc Interv Radiol 2009;32(1):19–24. https://doi.org/10.1007/s00270-008-9439-9.

[44] Miller DL, Kwon D, Bonavia GH. Reference levels for patient radiation doses in interventional radiology: Proposed initial values for U.S. practice. Radiology 2009;253(3):753–64. https://doi.org/10.1148/radiol.2533090354.

[45] Lee MY, Kwon J, Ryu GW, Kim KH, Nam HW, et al. Review of national diagnostic reference levels for interventional procedures. Prog Med Phys 2019;30(4):75–88. https://doi.org/10.14316/pmp.2019.30.4.75.

[46] Stratakis J, Damilakis J, Hatzidakis A, Perisinakis K, Gourtsoyiannis N. Radiation Dose and Risk from Fluoroscopically Guided Percutaneous Transhepatic Biliary Procedures. J Vasc Interv Radiol 2006;17(1):77–84. https://doi.org/10.1097/01.RVI.0000188754.97465.13.

[47] Heilmaier C, Zuber N, Berthold C, Kara L, Weishaupt D. Establishing Local Diagnostic Reference Levels in IR Procedures with Dose Management Software. J Vasc Interv Radiol 2017;28(3):429–41. https://doi.org/10.1016/j.jvir.2016.10.006.

[48] Padovani R, Bernardi G, Malisan MR, Va o E, Morocutti G, Fioretti PM. Patient dose related to the complexity of interventional cardiology procedures. Rad Prot Dosim 2001;94(1):189–92. https://doi.org/10.1093/oxfordjournals.rpd.a006469.

[49] Delichas MG, Psarrakos K, Hatziioannou K, Giannoglou G, Molyvda-Athanasopoulou E, Papanastassiou E, et al. The dependence of patient dose on factors relating to the technique and complexity of Interventional Cardiology procedures. Phys Med 2005;21(4):153–7. https://doi.org/10.1016/S1120-1797(05)80004-3.

[50] Zanca F, Collard C, Alexandre N, Deprez F, Salembier JP, Henry M, et al. Patient exposure data and operator dose in coronary interventional procedures: Impact of body-mass index and procedure complexity. Phys Med 2020;76:38–43. https://doi.org/10.1016/j.ejmp.2020.05.006.

[51] International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Approved by the Commission in September 2000. Oxford, Elsevier; 2001.

[52] Kwon D, Little MP, Miller D. Reference air kerma and kerma-area product as estimators of peak skin dose for fluoroscopically guided interventions. Med Phys 2011;38(7):4196–204. https://doi.org/10.1118/1.3590358.

[53] Jones AK, Ensor JE, Pasciak AS. How accurately can the peak skin dose in fluoroscopy be determined using indirect dose metrics? Med Phys 2014;41(7):071913. https://doi.org/10.1118/1.4884020.

[54] Malchair F, Dabin J, Deleu M, Merce MS, Bjelac OC, Gallagher A, et al. Review of skin dose calculation software in interventional cardiology. Phys Med 2020;80:75–83. https://doi.org/10.1016/j.ejmp.2020.09.023.