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Local diagnostic reference levels and effective doses: single institution levels for interventional cardiology procedures for adult patients

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Abstract

Introduction: The current regulations in Poland in the field of interventional radiology only include diagnostic reference levels (DRL) for five procedures, containing only two for cardiological (hemodynamic) procedures, and only for adults. Given the insufficient number of DRLs, the need to introduce local levels based on the intervention procedures performed was identified. The purpose of this research was the evaluation of radiation doses (DRL, effective dose) received by patients in cardiological interventional procedures.

Material and methods: The DRL level was defined as the 75th percentile of the distribution of dosimetric parameters KAP and $K_{air,ref}$ for each type of cardiological procedure. Data include three different X-ray units and 27 interventional cardiologists, derived from February 2019 to June 2019 and from August 2021 to December 2021. In order to estimate the effective dose, the appropriate conversion factors for cardiological procedures were used. The total number of analyzed procedures was 3818.

Results: The proposed local DRL levels were found to be mostly lower than data found in literature and in the current Polish national requirements (60%-70% lower for coronary angiography (CA) and percutaneous coronary angioplasty (PCI) procedures). Median equivalent doses for cardiological procedures were estimated at 2.66 mSv, 6.11 mSv and 7.22 mSv for CA, PCI and combined PCI with CA procedure, respectively.

Conclusions: The proposed local/institutional DRLs seem to be suitable for use and could be utilized by other centers for comparison purposes.

Keywords: effective dose; interventional cardiology; Diagnostic Reference Levels (DRL).

Introduction

The frequency of coronary angiography and PTCA (Percutaneous Transluminal Coronary Angioplasty) procedures, as well as computed tomography examinations, has increased significantly in recent years.[1] It is estimated that the effective dose from high-dose diagnostic procedures (computer tomography, interventional radiology) constitutes about 80% of the mean cumulative dose (i.e. the mean value of the total dose for a given population), while these procedures constitute only 10% of all diagnostic procedures using ionizing radiation.[2]

According to the definition included in the Polish Atomic Law Act (the regulations and definitions of which comply with EU directives), the diagnostic reference level (DRL) in interventional radiology is the level of ionizing radiation dose in typical diagnostic procedures to which patients with a standard body structure are subjected with regard to broadly defined categories of equipment. Some established and proposed DRL values for interventional radiology procedures are presented in **Table 1**.

Each X-ray unit used in interventional radiology procedures must be equipped with a system monitoring the dose received by the patient. The dosimetric parameters determined by this system include KAP (the product of the air kerma and the irradiated area, measured with an ionization chamber or determined on the basis of exposure parameters) and K_{air} (air kerma determined on the basis of the KAP parameter or could be calculated based on x-ray tube output for given technique factors and added filtration[3]). The first is used to estimate the risk of stochastic effects (e.g. cancer), while the second is an indicator related to deterministic effects (e.g. radiation damage to the skin).[4]

Authors' contribution: A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article.

Table 1. Diagnostic Reference Levels

	Type of procedure	KAP [Gy×cm²]
Valid in Poland[5]	Limb-pelvic venography	9
	Pelvic-limb arteriography	85
	Coronary angiography (CA)	60
	PTA – Percutaneous Transluminal Angioplasty	100
	PTCA – Percutaneous transluminal coronary angioplasty	120
Proposed in Europe for interventional cardiology[6]	Coronary angiography (CA)	35
	PCI – Percutaneous Coronary Intervention	85
	TAVI – Transcatheter Aortic Valve Implantation	130
	Electrophysiological procedures	12
	Pacemaker implantation – single-chamber	2.5
	Pacemaker implantation – two-chamber	3.5
	Pacemaker implantation of cardiac resynchronization	18

The KAP parameter is the best available tool for providing information about the total exposure of the patient's body in interventional radiology procedures. In the literature, there are factors for its conversion into an effective dose. The proposed conversion factor of KAP into an effective dose in the torso area is 0.2 mSv/Gy×cm^2.[7] KAP is also directly related to the amount of scattered radiation that reaches interventional radiology personnel.[7] For this example and without anti-radiation shields, it is assumed that 100 Gy×cm^2 corresponds to approximately 1 mGy of the dose absorbed by the X-ray unit operator's legs.[8]

Deterministic effects are caused by appropriately high doses of ionizing radiation, such as damage or tissue/cell death, which occur after exceeding the dose threshold. The severity of these effects and the time of their manifestation are dose-dependent, which becomes evident after exceeding a certain dose threshold characteristic of a given effect.[9] Low doses of ionizing radiation induce stochastic effects such as cancer or hereditary effects, although the latter is observed at a statistically significant level only in animal models.[7,10] The likelihood of these effects occurring depends on the dose. According to current knowledge, a linear, thresholdless relationship between exposure to ionizing radiation and the probability of cancer development in humans is widely adopted for risk management.[10]

The effective dose (E) is the sum of the equivalent doses (H_T) from external and internal irradiation in all organs (tissues), taking into account the relevant tissue/organ weighting factors.[11-13] Tissue weighting factors are averaged values for age and sex because E is determined for a reference person; therefore, the concept of an effective dose should be used for comparative purposes (for example, medical procedures, radiological devices) rather than for determining it for a specific person, where factors of age, gender and individual sensitivity to ionizing radiation play a role.[11]

The aim of the study was to determine the DRL level of KAP and $K_{air,ref}$ separately for each type of interventional cardiology procedure (diagnostic, diagnostic - treatment and treatment). The measurements were carried out in two measurement periods. The first introduces levels for the most frequently performed procedures (coronary angiography, percutaneous coronary angioplasty). The purpose of the data analysis from the second measurement period was to verify the previously derived levels, as well as to define new ones for other procedures.

Materials and methods

The research project was approved by the Bioethical Committee of the Medical University of Silesia in Katowice, decision NoKNW/0022/KB1/68/18 of September 25, 2018. The research was carried out at the Department of Invasive Cardiology at the Prof. Leszek Giec Upper Silesian Medical Center of the Medical University of Silesia in Katowice.

Based on data from cardiological procedures, diagnostic reference levels (DRL) were derived. Data include three different X-ray units and 27 interventional cardiologists, derived from two periods - from February 2019 to June 2019 and from August 2021 to December 2021. The total number of procedures in the first period was 1840 (CA - coronary angiography, PCI - percutaneous coronary angioplasty, CA + PCI), and in the second period, 1978 (CA - coronary angiography (with and without FFR, IVUS, OCT), PCI - percutaneous coronary angioplasty, CA + PCI (with and without FFR, IVUS), TAVI, PFO (Patent Foramen Ovale), pacemaker implantation). Only in the second measurement period the weights and heights of the patients were taken into account. The mean age of the patients for all procedures was 69, with a standard deviation of 11. Detailed data are presented in **Table 2**.

The DRL level was defined as the 75th percentile (3rd quartile) of the distribution of dosimetric parameters KAP and $K_{air,ref}$ separately for each type of procedure (diagnostic, diagnostic - treatment and treatment). The values displayed by radiological units were used. The interventional cardiologists had varied professional experience.

Table 2. Number of procedures for measurement period

Period	1st	2nd total	2nd *	height [cm] mean (SD)	weight [kg] mean (SD)
Procedures	**No of procedures**				
CA	1088	882	301	168 (12)	83 (19)
CI	66	99	30	172 (8)	85 (19)
CA + PCI	686	590	168	170 (9)	81 (16)
CA(FFR, IVUS, OCT)	—	65	32	172 (7)	84 (15)
CA + PCI(FFR, IVUS)	—	72	30	170 (8)	83 (14)
TAVI	—	56	—	—	—
PFO	—	18	16	168 (8)	78 (20)
Pacemaker implantation – single-chamber	—	73	39	171 (9)	82 (17)
Pacemaker implantation – two-chamber	—	123	60	171 (9)	83 (13)

**the number of procedures for which the weight and height of the patient were determined*

The K_{air} parameter measured at the beam entry point along the central axis of the ionizing radiation beam into the patient's body is called the entry kerma and does not take the effect of radiation scattered from the patient into account.[12] In interventional radiology, this point, located 15 cm from the isocenter of the X-ray unit towards the X-ray tube, is the intervention reference point (IRP). The entry kerma measured at this point ($K_{air,\ ref.}$) during the interventional procedure corresponds to the cumulative dose therein.[14]

KAP is the product of the air kerma (K_{air}) and the area of the X-ray field perpendicular to the central axis of the main beam of this radiation (A).[12] Assuming that kerma is constant over the entire field of the beam, which is approximately true for small fields, one may obtain K_{air}×A [Gy×cm^2].[15] The KAP parameter is independent in terms of distance, assuming that absorption and scattering in the air, as well as emissions from the part of the X-ray tube other than the focus, are negligible[15] and the location of the ionization chamber measuring KAP is such that the scattered radiation from the patient does not affect the measurement (it cannot be placed too close to the patient).[12] KAP parameter values are recommended as DRLs for general radiography as well as for interventional radiology procedures.[15]

Cardiological procedures were performed using Artis Zee Floor (Siemens, 2010), InfinixVf-i, (Canon, 2017) and AlluraXper FD 20 (Philips, 2011). The intervention reference point (IRP) is located in the Canon X-ray unit at the height of 590 mm, and in Siemens cameras at the height of 750 mm. Those X-ray units are subject to routine quality control tests carried out by qualified medical physicists employed at the hospital. All parameters measured during the tests met the test acceptance criteria (specified in the Polish legal requirements).

In order to estimate the effective dose (E), the following conversion factors (E/KAP) for cardiological procedures[16] were used:

CA: 0.30 ± 0.04 [mSv×Gy^{-1}cm^{-2}]

PCI: 0.33 ± 0.05 [mSv×Gy^{-1}cm^{-2}]

Statistical analysis was performed using Statistica (statistical data analysis and charting software), version 13.3. The normality of the distribution of variables was evaluated by means of the Shapiro-Wilk test, and additionally by the Kolmogorov-Smirnov test with the Lilliefors correction (for an unlimited number of cases). The Lilliefors correction was applied due to the lack of information about the mean and standard deviation for the entire population. In the case of variables characterized by a distribution deviating from the normal distribution, the median, quartile deviation - quartile range (describing the extent of the median environment) and skewness (asymmetry coefficient) were determined. The arithmetic mean was also determined in order to compare it with the median value. Graphical distributions of variables are presented by means of histograms.

Results

The determined levels of DRL are presented in **Table 3**, while **Table 4** contains the effective dose values.

Detailed data concerning the estimated values of effective doses were determined for the first measurement period (**Table 4**). In the second period, the mean and median of KAP decreased for CA by 24% and 35%, for PCI by 8% and 30% and CA + PCI 18% (the mean and median are the same). The mean value and median of the $K_{air,ref}$ parameter decreased for CA and CA+PCI. For PCI, these values were higher by 11% and 14%, respectively.

The distributions of the analyzed variables of KAP and $K_{air,ref}$ are characterized by a right-side asymmetry (the mean values of the studied parameters are greater than the medians), so they all differ in shape from the normal distribution, as evidenced by the results of the relevant tests (Shapiro-Wilk, Kolmogorov-Smirnov with the Lilliefors correction, $p < 0.01$). As the doses are optimized toward low values and exceeding the suggested limits is extraordinary, it is expected that dose distribution should be not-normal and asymmetrical.

Table 3. DRL and other statistical measures

Parameter	Mean		Median		Min / Max		75th percentile - DRL	
	1st	2nd*	1st	2nd*	1st	2nd*	1st	2nd*
CA								
KAP [Gy×cm^2]	14.35	10.91 (11.43)	8.86	5.83 (6.00)	0.42 / 16.25	0.01 / 96.00	16.06	11.02 (11.57)
$K_{air,ref}$ [mGy]	202.0	131.5 (135.8)	118.4	85.0 (90.0)	6.0 / 2628.0	4.0 / 1800.0	215.0	163.0 (172.0)
CA (FFR, IVUS, OCT)								
KAP [Gy×cm^2]	—	11.55 (11.83)	—	6.85 (6.44)	—	1.1 / 70.0	—	15.40 (13.00)
$K_{air,ref}$ [mGy]	—	284.2 (355.3)	—	197.0 (210.0)	—	18.0 / 3100.0	—	304.0 (317.0)
PCI								
KAP [Gy×cm^2]	26.63	24.33 (38.55)	18.52	12.90 (15.19)	3.79 / 92.95	0.57 / 362.06	36.67	29.00 (50.10)
$K_{air,ref}$ [mGy]	473.0	534.0 (720.0)	310.0	360.0 (333.6)	2.2 / 2313.0	22.0 / 4005.0	643.0	590.0 (956.0)
CA + PCI								
KAP [Gy×cm^2]	31.52	25.78 (32.80)	21.87	17.89 (22.46)	0.17 / 215.52	0.01 / 300.0	39.31	34.00 (41.12)
$K_{air,ref}$ [mGy]	490.0	452.5 (547.1)	339.0	321.1 (387.5)	0.4 / 3843.0	12.0 / 3875.0	642.0	577.0 (724.5)
CA + PCI (FFR, IVUS)								
KAP [Gy×cm^2]	—	20.10 (20.37)	—	16.00 (16.11)	—	0.20 / 97.00	—	25.40 (20.40)
$K_{air,ref}$ [mGy]	—	361.3 (399.5)	—	260.0 (275.0)	—	18.0 / 3100.0	—	457.0 (349.0)
TAVI								
KAP [Gy×cm^2]	—	66.35	—	49.55	—	0.60 / 534.00	—	80.0
$K_{air,ref}$ [mGy]	—	354.1	—	300.2	—	91.6 / 983	—	468.5
PFO								
KAP [Gy×cm^2]	—	5.30 (5.73)	—	3.56 (3.79)	—	0.45 / 13.1	—	8.95 (9.48)
$K_{air,ref}$ [mGy]	—	22.9 (24.4)	—	14.7 (14.7)	—	6.0 / 51.0	—	43.0 (43.5)
Pacemaker implantation - single-chamber								
KAP [Gy×cm^2]	—	4.59 (3.13)	—	2.20 (2.20)	—	0.21 / 36.60	—	5.04 (3.64)
$K_{air,ref}$ [mGy]	—	21.3 (15.7)	—	9.0 (8.8)	—	1.0 / 125.0	—	24.0 (11.0)
Pacemaker implantation - two-chamber								
KAP [Gy×cm^2]	—	6.10 (6.46)	—	3.31 (2.99)	—	0.06 / 40.96	—	6.89 (7.46)
$K_{air,ref}$ [mGy]	—	33.0 (37.0)	—	19.5 (22.5)	—	2.0 / 188.7	—	47.0 (47.0)

**the values in parentheses are for the procedures for which the weight and height of the patient were determined*

Table 4. Estimated values of effective doses

Procedures	Number of procedures	Conversion factors from KAP to E	Estimated values of effective doses				
			Mean	Standard deviation	Min / Max	Median	Quartile deviation
CA	1088	0.3 mSv/(Gy×cm^2)	4.30	5.39	0.12 / 48.75	2.66	3.42
PCI	66	0.33 mSv/(Gy×cm^2)	8.79	7.39	1.25 / 30.67	6.11	8.78
CA+ PCI	686	0.33 mSv/(Gy×cm^2)	10.40	9.93	0.06 / 71.12	7.22	8.78

Discussion

In 2014, one of the most comprehensive and complete reports on the state of DRL levels in European countries, the Dose Datamed 2 project, was published – and is still considered valid.[17] According to this report, of the 36 countries participating in the study, only eight of them had their own levels of DRL for interventional radiology. The current regulations in Poland in the field of interventional radiology only include levels for five procedures, containing only three for procedures other than hemodynamic, and only for adults. Taking the lack of a sufficient number of diagnostic reference levels into account, a bespoke DRL was derived based on the intervention procedures analyzed in this project. According to the recommendation of the International Health Organization, DRL levels should be determined on the basis of easily measurable parameters[18]; hence, they were determined for the parameters $K_{air,ref}$ and KAP.

The fluoroscopy time (t) itself is not a good indicator of exposure to ionizing radiation[19,20] and should be used in conjunction with other data as it only provides information on the duration of fluoroscopy in the absence of important information such as X-ray dose rate or pulsed fluoroscopy parameters, and therefore was not included when determining DRL in this study.

All the reference levels determined on the basis of our research are at a level much lower than the proposed levels that may cause skin lesions ($K_{air,ref}$ = 5 Gy, KAP = 500 Gy × cm^2).[2]

Our local reference levels for invasive cardiology procedures are much lower than the levels currently recommended in our country.[5] Moreover, they are lower than those recommended in Europe,[6] as well as in other studies available in the literature (2008),[18] but they are slightly higher than the DRL levels in Poland reported in 2018 by Siiskonen et al.,[6] who did not include CTO (chronic total occlusion) procedures.

In our research, CTO procedures are included in the scope of PCI procedures; hence, the higher value of the DRL levels set by us. Ultimately, the levels of DRL in Europe proposed by Siiskonen et al. for the full group of patients and all analyzed countries are higher than ours. It is noteworthy that these levels were slightly lower than our results for only two of 13 countries (Poland, and Lebanon). It is worth emphasizing that in the studies to date, there are limited data available on the levels of DRL determined by the kerma at the reference point. This parameter depends strictly on the location of the isocenter of X-ray treatment units. Different manufacturers set an isocenter at different distances from the X-ray tube focus, which was specified in the methodology of this study. For example, Stratis et al. proposed lower DRL values for CA and PCI (expressed using the mean entry dose (Gy)).[18] These levels were determined on the basis of the dose at the height of 70 cm (the average value of the table height from the X-ray tube focus in these studies). The values given by us refer to the measurement at the reference point (average value of 67 cm), while in our research, the Canon x-ray unit (59 cm) was used more often. In addition, the above-mentioned study did not provide detailed information on the complexity of intervention procedures (PCI without/with CTO). The literature also provides DRL values for $K_{air,ref,}$ which are significantly higher than those determined in our studies, and also higher than 2 Gy, which is undesirable from the point of view of radiation skin changes.[21] When comparing DRL levels determined on the basis of the K_{air}, the distance at which the kerma was determined should be taken into account. Unlike K_{air}, the KAP parameter does not depend on the distance from the radiation source, so this parameter seems to be more practical in terms of global comparisons of DRL levels.

Since the distribution of KAP and K_{air} values for each analyzed procedure deviates from the normal distribution, the median value was used for the purpose of comparing the estimated effective doses. The values of effective doses taken from the literature clearly suggest the need to estimate the effective doses locally in order to be able to precisely determine the exposure of patients (the range between doses is even an order of magnitude for the same type of procedure).[7] In a study by Brambilla et al.[16], effective doses slightly higher than ours were estimated (despite the use of the same conversion factors). The applied conversion factors were determined on the basis of measurements carried out in clinical conditions (65 patients, including 34 CA, 31 PCI). There is no doubt that the applied exposure conditions had an influence on the results obtained. In the work of Brambilla et al., an X-ray unit with additional copper filtration was used, which was not activated in the image acquisition mode, and an image registration of 15 frames per second in the fluoroscopy and acquisition mode. The X-ray units used in our center have active additional filtration in both modes, while the basic frame rate is 7.5 frames per second. Similarly, higher values of effective doses were obtained during measurements with the use of an anthropomorphic phantom.[22] The average risk of developing cancer as a result of exposure to ionizing radiation for the effective dose estimated by a group of researchers from Greece of 4.3 mSv (coronary angiography) and 9.85 mSv (PCI) was 0.02% and 0.05%, respectively.[18] Therefore, it can be assumed that for the estimates obtained in our study, the risk may be at a similar level. Finally, it should be noted that although the effective dose has some limitations (it cannot be used to assess the risk for a given patient), it can still be an important comparative parameter used in radiological protection. In establishing constant (for a given anatomical location) conversion factors, this dose will depend solely on the KAP parameter.

The DRL levels determined in this study, as well as the estimated effective doses, for procedures other than CA, PCI, and CA with PCI, need to be extended to the full range of intervention procedures.

Conclusions

The number of procedures included in the presented study is high enough to be representative of interventional radiology procedures performed at our center. Therefore, the proposed local/institutional DRLs seem to be suitable for use and could be utilized by other centers for comparison purposes. Moreover, the values obtained in the presented research include the isocenter parameter practically applied in X-ray units widely used in interventional radiology worldwide. ICRP Publication 89 specifies values of height and weight for a reference person at the levels of 176 cm/73 kg and 163 cm/60 kg for men and women, respectively.[23] As can be seen in **Table 2**, the average patients for which the presented analysis was performed were slightly heavier (~20%) than the reference person, while the height was maintained at a reference level.

Even in this case, the analysis performed in the presented study has shown that the current national requirements concerning DRL levels based on the KAP parameter could be lowered even by 70% for CA and PCI procedures (14.35 vs. 60 Gy×cm^2) performed individually, or by at least 60% taking into account these procedures performed together (31.52 vs. 85 Gy×cm^2). For the TAVI procedure, our DRL could be lowered in comparison with European recommendations by approximately 50%; however, KAP values for pacemaker implantation are at the same level as European recommendations or exceed them by almost a factor of two when median or mean values from our analysis are used, respectively.

Since some procedures from interventional radiology widely performed in cardiological clinics are not clearly specified in current national regulations, the analysis presented in this study could help to fill this gap.

For CA, PCI, and CA+PCI procedures, we are going to use DRL's derived in the second period of measurement on account of more up-to-date data, lower values for CA and CA + PCI procedures, and for PCI because of a larger number of analyzed procedures. There was no noticeable change in clinical practice applied between the analyzed periods, and any change could be just accidental and because of statistical reasons.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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