Eur Radiol (2012) 22:1240–1249
DOI 10.1007/s00330-012-2386-5

INTERVENTIONAL

A national patient dose survey and setting of reference levels for interventional radiology in Bulgaria

R. Zotova · J. Vassileva · J. Hristova · M. Pirinen · H. Järvinen

Received: 5 September 2011 / Revised: 6 December 2011 / Accepted: 21 December 2011 / Published online: 19 February 2012

Abstract
Objectives A national study on patient dose values in interventional radiology and cardiology was performed in order to assess current practice in Bulgaria, to estimate the typical patient doses and to propose reference levels for the most common procedures.
Methods Fifteen units and more than 1,000 cases were included. Average values of the measured parameters for three procedures—coronary angiography (CA), combined procedure (CA+PCI) and lower limb arteriography (LLA)—were compared with data published in the literature.
Results Substantial variations were observed in equipment and procedure protocols used. This resulted in variations in patient dose: air-kerma area product ranges were 4–339, 6–1,003 and 0.2–288 Gy cm^2 for CA, CA+PCI and LLA respectively. Reference levels for air kerma-area product were proposed: 40 Gy cm^2 for CA, 140 Gy cm^2 for CA+PCI and 45 Gy cm^2 for LLA. Auxiliary reference intervals were proposed for other dose-related parameters: fluoroscopy time, number of images and entrance surface air kerma rate in fluoroscopy and cine mode.
Conclusions There is an apparent necessity for improvement in the classification of peripheral procedures and for standardisation of the protocols applied. It is important that patient doses are routinely recorded and compared with reference levels.

R. Zotova (✉) · J. Vassileva · J. Hristova
National Centre of Radiobiology and Radiation Protection, Sofia, Bulgaria
e-mail: r.borisova@gmail.com

M. Pirinen · H. Järvinen
Radiation and Nuclear Safety Authority (STUK), Helsinki, Finland

Key Points
- *Patient doses in interventional radiology are high and vary greatly*
- *Better standardisation of procedures and techniques is needed to improve practice*
- *Dose reference levels for most common procedures are proposed*

Keywords Interventional radiology · Interventional cardiology · Radiation protection · Patient dosimetry · Patient dose · Reference levels

Introduction

Interventional radiology has exhibited remarkable growth in popularity over the last few years. However, due to their significant length, complexity and high image quality requirements, the procedures involved are characterised by substantial patient and staff exposure. Additionally, the World Health Organisation, the International Commission on Radiation Protection and other international authorities have remarked on the fact that such procedures are frequently performed by professionals with insufficient knowledge and awareness of radiation effects and dependence on the technical and exposure parameters [1, 2].

The number of X-ray units for interventional radiology applications increased from 20 in 2007 to 37 in 2010. A quality assurance programme of interventional procedures was recently introduced and is still effectively applied throughout the country. There was practically no information on the actual condition and characteristics of the angiography units in operation, or on the doses that patients receive during such procedures. For this reason at the beginning of 2007 the National Centre of Radiobiology and

Radiation Protection (NCRRP) launched a nationwide study on patient exposure in interventional diagnostic and therapeutic procedures performed in Bulgaria, under the governance of the Ministry of Health. The study was also partially conducted under the SENTINEL EU Coordinated Action Project, IAEA Regional Project R9/093 and Finland–Bulgaria PHARE Twinning Project BG 2006/IB/SO 01. The purpose of the study was to obtain and summarise the information on the type and number of interventional procedures performed in the country and to assess the patient doses for the most commonly performed procedures. The ultimate purpose was to develop recommendations for optimisation of the procedures in order to decrease patient and staff exposure while maintaining adequate diagnostic and therapeutic quality, and to propose national reference dose levels for the most common procedures.

Materials and methods

Dose quantities

In order to characterise patient exposure in interventional procedures, the following dosimetric quantities were used:

Air kerma-area product (P_{KA})—this quantity is strictly defined as the integral of the air kerma over the area of the beam in a plane, perpendicular to the central axis of the X-ray beam [3, 4]. With certain limitations this definition can be simplified to the product

$$P_{KA} = K_{air}(z)A_z$$

where $K_{air}(z)$ is the air kerma measured on the central axis of the beam at a distance z from the focal spot, and A_z is the field area in a plane, perpendicular to the central axis of the beam at the same distance z [5]. As $K_{air}(z)$ decreases with the square of the distance from the focus z, while the field area A_z increases with the same factor, the product of the two remains invariant with regard to the distance from the focus of the X-ray tube. The unit for air kerma–area product is Gy m^2; its derivatives μGy m^2, Gy cm^2 and others are also frequently used. In many references this quantity is also denoted by *KAP*.

P_{KA} is informative of the risk of stochastic effects in patients and is the only measurable quantity in complex combined examinations that involve a series of radiographic and fluoroscopic images with a constantly changing focus-patient skin distance, exposure parameters and field size. P_{KA} also provides information about field collimation, which is a very effective way of both decreasing patient and staff dose and enhancing image quality.

P_{KA} can be measured by a KAP meter: a transmission plate-parallel ionisation chamber connected to an electrometer and mounted on the exit surface of the X-ray tube, below or over the housing. KAP meters should be calibrated by the local medical physics staff every time they are installed on an X-ray unit, following major repair or upgrade of the unit or otherwise at least once a year [6]. The calibration factor derived during calibration depends strongly on exposure parameters such as field size, collimation, mode of operation, tube current and voltage, and therefore has to be determined individually for all commonly used sets of conditions.

The uncertainty of the calibration factor derived in this manner was estimated using the principles outlined in the guide to the expression of uncertainty in measurement and in the IAEA code of practice for dosimetry in diagnostic radiology [3, 7].

Cumulative dose (CD)—the absorbed dose in air at the interventional reference point (IRP). For systems with an isocentre this is a point on the reference axis, 15 cm from the isocentre towards the focal spot [8]. This distance is assumed to represent a good approximation of the value of the actual focus–skin distance during interventional procedures and thus with certain limitations the cumulative dose could be used as rough guidance to the risk of the occurrence of deterministic skin injuries; however, this is a good approximation only if the procedure involves just one beam projection. In actual interventional procedures where beams at many different angles are employed, the relationship between CD and the maximum skin dose (MSD) is not straightforward. Depending on the type and geometry of the procedure and the projections used, CD can either underestimate or overestimate MSD. The relationship between CD and MSD should be studied for a sample of patients on each unit before CD can be used as a reliable indication for MSD [9, 10].

Entrance surface air kerma rate (ESAK rate)—the air kerma rate measured at the surface of a phantom, including backscatter radiation [3]. This quantity is introduced to characterise the equipment and its settings in the different modes of operation. Non-optimal settings of the X-ray equipment used for interventional procedures are a common reason for higher typical patient dose values. It is therefore important that the ESAK rate is measured for all available fluoroscopy and cine modes during the commissioning of new angiography equipment, as well as after major changes or repairs.

Data collection and measurements

For collection of the data and for P_{KA} measurements and KAP meter calibrations, ten cardiology suites and five radiology departments throughout the country were visited.

The most common procedures performed at each unit were recorded. Data collection for every procedure comprised the following information: procedure type and complexity, patient data (sex, age, weight and height), procedure parameters (fluoroscopy time [*FT*], number of images [*N*], pulse rate and frame rate used) and patient dose information (air

kerma–area product [P_{KA}] and cumulative dose [*CD*], where possible). Information was collected for at least 20 consecutive patients per centre per procedure. Data were collected by members of the NCRRP with the assistance of the local hospital staff, and a visit was made to install and/or calibrate the available air kerma–area product meter and to record general information about the practice in the angiography department.

Air kerma–area product was either recorded from the readings of the angiography units or measured by externally mounted KAP chambers of the DIAMENTOR M4 KDK and DIAMENTOR E2 (PTW Freiburg, Germany). Cumulative dose was recorded from the readings of the units and on one occasion measured by the DIAMENTOR M4 KDK.

All units had their KAP meters calibrated once, usually in the middle of the data collection period for the corresponding department. Calibration was performed in PA projection by measuring the air kerma at the central beam axis and the field size at the same distance from the focus. Air kerma was measured by a UNIDOS E dosimeter with diagnostic ionisation chambers 34060 and 34069 (PTW Freiburg, Germany). The chamber was positioned at a minimum of 20 cm above the patient couch to reduce the scatter influence and to take into account the attenuation of the couch and the mattress. The field size in the chamber plane was determined from the cross-sectional area of the field in the image intensifier plane, corrected with the magnification factor, obtained by comparing the real diameter of the ionisation chamber and the diameter of its image. Where possible, calibrations were performed for each available field of view (FoV), fluoroscopy and cine mode at three values of the tube voltage: approximately 60, 80 and 100 kV. A calibration factor (CF) was derived for each set of conditions, defined as the conventionally true P_{KA} value (the product of K_{air} measured with the reference dosimeter and the field size determined at the same point) divided by the P_{KA} value measured by the unit KAP meter. Patient dose calculations employed calibration factors averaged over the clinically used modes.

The same dosimetric system UNIDOS E was used to measure the entrance surface air kerma rate in fluoro mode and ESAK per image in acquisition on each unit. Patients of different thicknesses were simulated with a range of polymethyl methacrylate (PMMA) phantoms—16, 20, 24 and 30 cm. The ionisation chamber of the dosimeter was fitted closely between the patient couch and the phantom (under-couch geometry) in order to measure the air kerma incident on the patient skin, together with contribution from backscatter radiation. During the measurements with different phantom thicknesses the couch and image detector were moved accordingly to ensure that the centre of the phantom was at the isocentre and the image detector was approximately 5 cm from the phantom surface.

Angiography units

A total of 15 units were included in the study, constituting 41% of all angiography units in the country, by four different manufacturers and with different detector systems (flat panel detectors and image intensifiers). The units were located in six Bulgarian towns. Half of the units were selected in the capital city, where a great proportion of the interventional practice is concentrated; the rest were chosen to be in different towns to represent different regions in the country. Both large university and regional hospitals and small specialised cardiac centres (including private ones) were represented.

Table 1 presents basic data on the angiography units included in the study: type and manufacturer of the unit and type and size of the image detector used.

Results

Angiography equipment

Calibration of KAP meters

As indicated above, all KAP meters were calibrated in situ during the data collection period. The calibration factors obtained exhibited great variations, both on average among the units and individually on a single unit depending on the

Table 1 Basic parameters of the angiography units included in the study: type and manufacturer, type of the image detector—image intensifier (II) or flat detector (FD)—and size of image detector (diameter for II and width for FD)

Type and manufacturer	Detector type	Detector size
Cardiology units		
Philips Integris Allura	Image Intensifier	23 cm
Philips Integris Allura	Image Intensifier	23 cm
Philips Integris Allura	Image Intensifier	23 cm
Shimadzu HeartSpeed	Image Intensifier	23 cm
Siemens BICOR T.O.P.	Image Intensifier	23 cm
Siemens Axiom Artis	Flat detector	20 × 20 cm
Siemens Axiom Artis	Image Intensifier	23 cm
Siemens Axiom Artis	Image Intensifier	23 cm
Siemens Coroscop	Image Intensifier	23 cm
Siemens Coroscop	Image Intensifier	33 cm
Radiology units		
GE Innova 4100	Flat detector	40 × 40 cm
Philips BV300	Image Intensifier	31 cm
Philips Integris V5000	Image Intensifier	38 cm
Siemens Coroscop HS	Image Intensifier	23 cm
Siemens Polystar	Image Intensifier	23 cm

field size, tube voltage and mode used (Table 2). The relative expanded uncertainty (k=2) of the calibration factors for each individual set of conditions was estimated to be approximately 7%.

All patient dose data presented further in this work are corrected with the corresponding P_{KA} calibration factor.

Dose parameters of the equipment

The major part of the cardiology units were typically operated in pulsed fluoro mode at a pulse rate of 15 pps or 30 pps. The most commonly used frame rate in cine mode was 12.5 fps or 15 fps (30 fps for paediatric patients). The parameters typically employed on the radiology units varied greatly depending on the unit and the procedure. Similarly, the relative share of the most commonly applied field of view sizes (FoV) also varied significantly depending on the application.

The results from the phantom measurement of the ESAK rate performed with a standard 20-cm PMMA phantom and at a field of view of approximately 23 cm in the three widely available fluoro modes (low, normal and high) are presented in Fig. 1. The ESAK rate in cine mode measured with a 20-cm PMMA phantom for the routinely used frame rate is presented in Fig. 2.

The ESAK rate on one of the angiography units for four different thicknesses of the PMMA phantom is presented on Fig. 3 in order to illustrate the dependence of the ESAK rate on patient thickness and/or the angulation of the projection used.

Patient doses and reference levels

Overall, more than 1,000 cases of various procedure types were collected in the study. All cardiology departments performed the two most common cardiology procedures: coronary angiography (CA) (performed on adults or paediatric patients) and a combined procedure of diagnostic angiography and percutaneous coronary intervention (angioplasty and/or stent placement).

Table 3 presents the results for the ten most common diagnostic and therapeutic procedures. As the collected data exhibit asymmetric and typically non-Gaussian distributions, samples are characterised by the mean and median values, the third quartile and the range (minimum to maximum value) of P_{KA}, FT, N and CD. The sample size and the number of participating units are also indicated.

The mean P_{KA} values for diagnostic procedures for the ten cardiology units varied greatly, at a maximum by a factor of 5.8. The average contribution of P_{KA} during operation in cine mode to the total P_{KA} value was 59%. The histogram for the P_{KA} values of all collected cases is presented in Fig. 4.

The mean P_{KA} values for combined CA+PCI procedures for the different units varied at maximum by a factor of approximately 5. The distribution of the individual P_{KA} values is shown on Fig. 5. The average contribution of P_{KA} during operation in cine mode to the total P_{KA} value amounted to 39%.

Lower limb arteriography was the only peripheral procedure for which a sufficiently large sample was accumulated. Great variations were observed here with respect to the

Table 2 Calibration factors (CFs) for the different units: average, minimum and maximum values, minimum to maximum ratio; average CF depending on field size and tube voltage, and cine to fluoro CF ratio. Values are presented for small (< 13 cm), medium (13–19 cm) and large (> 19 cm) field of view (FoV), and for low (60 kV), medium (80 kV) and high (100 kV) tube voltage. For units where calibration was performed under a single set of conditions, CF is represented only by the average value

Unit	Mean CF	Minimum	Maximum	Minimum/maximum	FoV (cm)			Tube voltage (kV)			Cine/ fluoro
					Small	Medium	Large	Low	Medium	High	
I	0.89	0.83	0.94	0.88	–	–	–	0.86	0.89		–
II	0.81	0.76	0.84	0.91	–	–	–	0.84	0.80	0.81	–
III	0.7	–	–	–	–	–	–	–	–	–	–
IV	1.09	–	–	–	–	–	–	–	–	–	–
V	0.68	0.64	0.79	0.80	0.79	0.71	0.67	0.65	0.67	0.73	–
VI	0.95	–	–	–	–	–	–	–	–	–	–
VII	0.55	0.48	0.60	0.81	0.52	0.50	0.48	–	–	–	0.86
VIII	0.64	0.58	0.66	0.88	0.61	0.66	0.64	–	–	–	0.90
IX	0.74	0.58	0.80	0.73	0.77	0.78	0.80	–	–	–	0.74
X	0.58	0.57	0.60	0.94	–	0.57	0.59	–	–	–	1.00
XI	0.64	0.57	0.69	0.82	0.59	0.67	0.66	–	–	–	1.04
XIII	0.59	0.54	0.62	0.87	–	0.58	0.60	–	–	–	0.87
XIV	0.65	0.56	0.65	0.86	–	–	–	–	–	–	0.87
XV	0.77	0.71	0.83	0.86	0.78	0.76	0.78	0.72	0.80	0.83	0.98

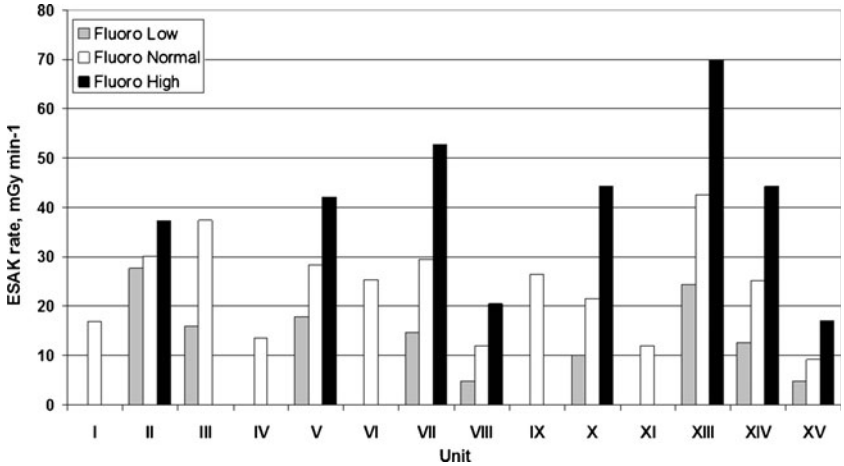

Fig. 1 The ESAK rate in fluoroscopy mode (in mGy min^{-1}), measured with a 20-cm polymethyl methacrylate (PMMA) phantom at a FoV of approximately 23 cm, and in normal, low and high dose fluoro modes

manner in which the procedure was carried out and the cine rate used, the latter ranging from 0.5 fps to as high as 12.5 fps. The minimum mean P_{KA} value differed from the maximum by a factor of 8. The third quartile value of 47 Gy cm^2 for total P_{KA} compares rather well with the value of 68 Gy cm^2 obtained as an average of several European IR units [11]. The contribution from P_{KA} in cine mode also varied greatly with an average value of 39%. The distribution of the individual P_{KA} values on all units is presented in Fig. 6.

Reference levels

The sample size was sufficient for the elaboration of reference levels for P_{KA} for only three procedures: CA, CA with a subsequent intervention (CA+PCI) and lower limb arteriography (LLA). Auxiliary reference intervals were specified for the other two dose-relevant quantities: fluoroscopy time and number of images. The reference levels for P_{KA} were elaborated based on the third quartile for the corresponding sample, and considering the reference values derived from similar national or multinational studies published in the literature. The auxiliary intervals were defined using the interquartile range of the samples (the range between the second and the third quartile). The reference levels and reference intervals are presented in Table 4.

Table 5 presents reference dose values proposed in different national and multinational studies, reported in literature.

Discussion

KAP meter calibration and dose parameters of the equipment

No clear conclusion could be drawn from the data regarding the way the different parameters affect the calibration factor.

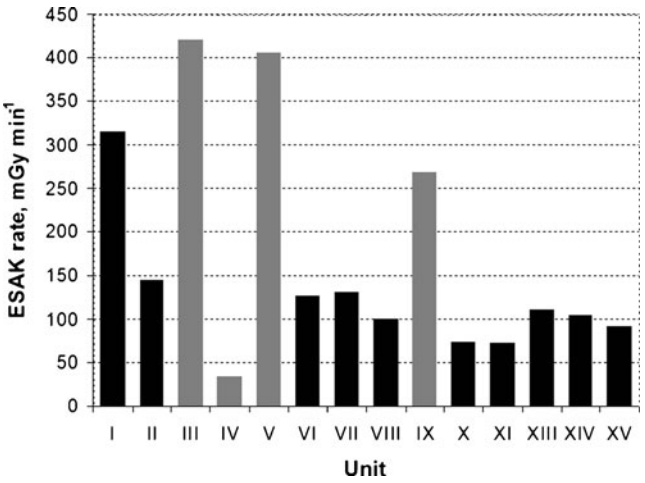

Fig. 2 The ESAK rate in cine mode (in mGy·min^{-1}), measured with a 20-cm PMMA phantom at a FoV of approximately 23 cm, and at the frame rate normally used on the corresponding unit. Units dedicated to radiology procedures are presented in *grey*

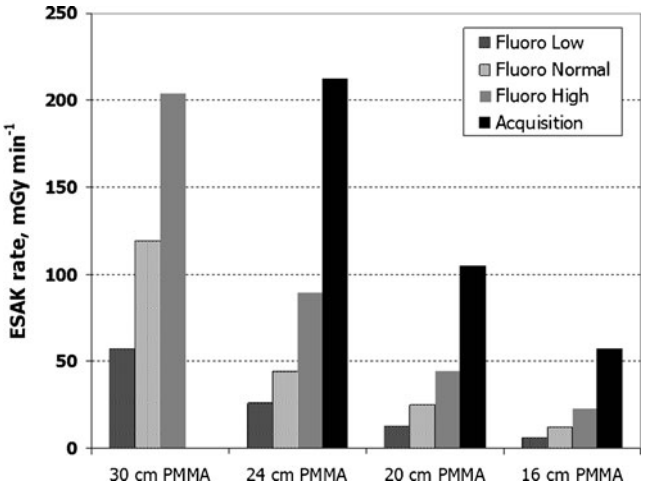

Fig. 3 The ESAK rate on one of the angiography units in the three available fluoro modes and in cine mode (in mGy s^{-1}), measured at FoV=23 cm for four different thicknesses of the PMMA phantom

Table 3 Results for the ten most common diagnostic and therapeutic interventional procedures. Samples are characterised by mean, median, third quartile value and the range (minimum to maximum value) for the four dose-related quantities: fluoroscopy time (in minutes), number of images per procedure, air kerma–area product (in Gy cm^2) for the entire procedure and for cine and fluoroscopy mode, and cumulative dose (in mGy)

Procedure	Sample size	No. units		Fluoroscopy time (min)	Number of images	Air kerma–area product P_{KA}, Gy cm^2			Cumulative dose (mGy)
						Total	Cine	Fluoro	
Diagnostic procedures									
CA	409	10							
			Mean	5.1	594	30	17	17	417
			Median	3.5	542	21	14	8	321
			3rd quartile	6.2	718	34	20	18	461
			Range	0.1–46.2	141–2073	4–339	3–181	1–265	75–1322
CA (paediatric)	15	1							
			Mean	11.4	538	5	2	3	54
			Median	9.8	437	4	1	3	43
			3rd quartile	13.5	814	6	2	4	77
			Range	4.0–25.1	92–1118	1–16	0.1–9	0.3–8	11–130
LLA	182	6							
			Mean	2.4	204	37	28	8	123
			Median	1.7	164	24	20	4	83
			3rd quartile	2.9	267	47	35	8	141
			Range	0.2–16.0	37–710	0.2–288	2–202	0.3–87	20–986
BA	67	5							
			Mean	10.5	298	36	16	23	279
			Median	8.0	211	30	13	15	229
			3rd quartile	12.2	365	41	23	29	379
			Range	0.2–39.6	43–1513	6–152	1–87	1–111	104–465
PhG	41	4							
			Mean	0.7	247	11	10	1	129
			Median	0.3	205	5	5	0.1	129
			3rd quartile	1.1	326	12	11	1	130
			Range	0.03–4.0	51–640	0.3–60	0.4–48	0–13	126–131
MG	9	1							
			Mean	14.1	278	200	121	79	584
			Median	13.4	290	181	74	60	428
			3rd quartile	20.9	321	243	133	110	982
			Range	1.4–31.2	101–500	13–554	12–337	1–217	76–1098
Therapeutic procedures									
CA+PCI	181	10							
			Mean	16.2	1381	98	54	66	1672
			Median	11.8	1210	67	38	39	1244
			3rd quartile	19.9	1625	114	63	72	2108
			Range	1.7–70.3	398–3986	6–1003	8–303	1–701	207–4927
PTC	21	2							
			Mean	7.5	60	31	3	31	
			Median	6.3	56	27	3	26	
			3rd quartile	9.2	70	42	4	42	
			Range	1.7–20.9	15–138	3–92	1–6	4–87	
PTA	41	2							
			Mean	9.5	20	27	18	15	163
			Median	6.5	14	21	11	13	124

Table 3 (continued)

Procedure	Sample size	No. units		Fluoroscopy time (min)	Number of images	Air kerma–area product P_{KA}, Gy cm^2			Cumulative dose (mGy)
						Total	Cine	Fluoro	
			3rd quartile	15.0	27	42	20	18	238
			Range	0.7–32.1	8–51	0.3–92	2–79	2–40	22–383
PhG+VCF	5	1							
			Mean	2.2	226	22	16	6	92
			Median	2.5	200	18	12	7	47
			3rd quartile	3.0	290	23	15	7	81
			Range	1.1–3.0	160–300	14–41	4–37	4–10	36–252
RA+E	3	1							
			Mean	16.6	94	104	8	96	
			Median	2.5	4	200	18	12	
			3rd quartile	3.0	5	290	23	15	
			Range	7.7–22.0	46–141	31–153	4–14	24–139	

CA coronary angiography, *LLA* lower limb arteriography, *BA* brain arteriography, *PhG* phlebography, *MG* mesentericography, *CA + PCI* coronary angiography + intervention, *PTC* biliary intervention, *PTA* stent placement, *PhG + VCF* phlebography + VC filter placement, *RA + E* renal arteriography + embolisation

In half of the units from which this information was collected, increasing the field size led to a decrease in CF. However, in the other half of the units, CF increased or remained the same as the FoV increased. Data were insufficient to determine any trends regarding the influence of tube voltage on CF. With respect to the variation with clinical mode, most of the units exhibited a slightly lower calibration factor for cine mode compared with that for fluoroscopy mode. Overall, it can be suggested that the variation of the calibration factor with the field size, tube voltage and mode of operation depends greatly on the technical adjustments of the unit and cannot be predicted. Therefore, wherever possible, calibration of the KAP meter should be performed for several sets of conditions, and an average calibration factor should be used to correct patient dose values.

The ESAK rate was found to vary substantially among the three fluoro modes: 5–28, 9–43 and 17–70 mGy min^{-1} for fluoro low, normal and high respectively, the average values being 15, 24 and 41 mGy min^{-1}. As can be seen, the difference between the lowest and the highest values reaches as high as sixfold in the case of low fluoro mode. This variation is consistent with the variation by a factor of 6–14 observed in several European IR units [11].

Regardless of the availability of at least two different fluoroscopy modes (normal, low and/or high dose modes), it was the normal fluoro mode that was typically employed

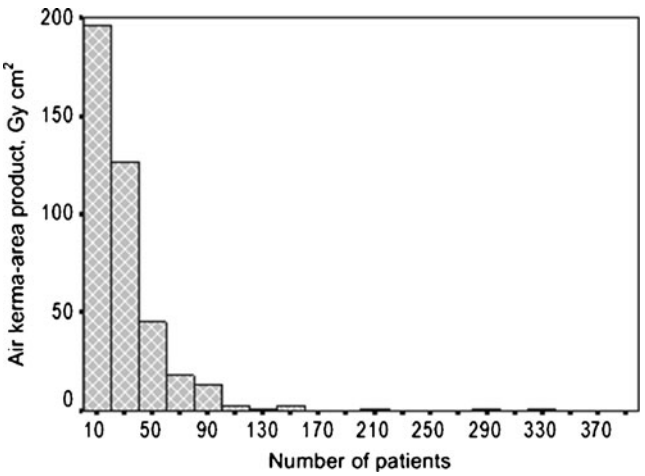

Fig. 4 Distribution of air kerma-area product (Gy cm^2) for coronary angiography (CA)

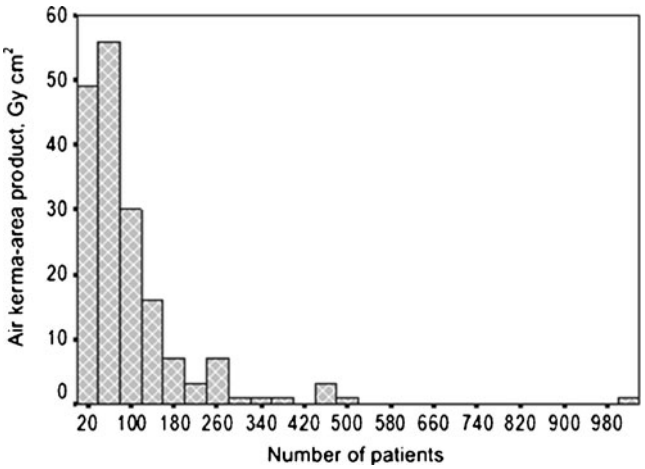

Fig. 5 Distribution of air kerma–area product (Gy cm^2) for combined coronary angiography and percutaneous coronary intervention (CA+PCI)

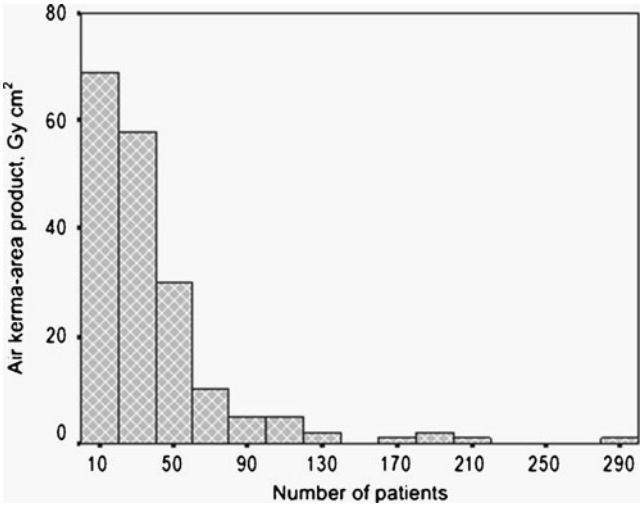

Fig. 6 Distribution of air kerma–area product (Gy cm^2) for lower limb arteriography (LLA)

on practically all units. However, from the results for the individual units it was calculated that the transition from normal fluoro mode to low reduces the ESAK rate by an average factor of 0.5. On the other hand, the application of the high fluoro mode instead of normal increases the ESAK rate at the phantom entrance with a mean factor of 1.7. It is therefore important for the medical team working on an angiography unit to be familiar with its different modes of operation and to use high-dose modes cautiously.

The ESAK rate in cine mode was found to vary between 0.6 mGy s^{-1} and 7 mGy s^{-1}, with a corresponding difference in ESAK per image of 0.28 mGy to 2.8 mGy. Figure 3 also clearly demonstrates the fivefold increase in the ESAK rate observed for all phantom thicknesses during transition from fluoro normal mode to cine mode.

Patient doses

CA procedures were found to be sufficiently standardised, with an almost constant set of projections applied, although in two of the departments the diagnostic coronary angiography procedure included acquisition series of additional non-coronary blood vessels. The classification of the peripheral procedures was noticeably less elaborated: various names were used in different departments for practically the same procedure, or the protocol used for a specific procedure varied substantially among the different departments. Additionally, certain specialisation of interventional radiology departments was observed: more than half of the peripheral procedures were performed on a single X-ray unit only, which rendered the comparison of different units impossible for the greater part of the peripheral procedures.

Patient dose was influenced by a broad range of factors such as angiography unit characteristics (ESAK rate in fluoroscopy and cine mode), patient characteristics, modes and magnifications used, and skills, experience and radiation protection awareness of the cardiologist.

As could be expected, the combined diagnostic and therapeutic coronary procedure (CA+PCI) was characterised by significantly greater patient exposure.

Both the diagnostic and the combined procedures exhibited positively skewed distributions, typical for these types of samples. The distribution of the individual P_{KA} values (Fig. 6) features a longer tail and more outlying extreme values (compared with the distribution for CA procedures), conditioned by the greater dependence on case specificity and complexity.

The variation found among the mean P_{KA} values is in agreement with the results of a recent European study, which reported variability of more than 3 among mean values taken from different units [12].

Reference levels

Reference levels were proposed for the air kerma–area product, fluoro time and number of images, as the three most readily available patient dose-relevant parameters. As the ESAK rate in the different imaging modes was found to have a significant influence on patient doses, auxiliary reference intervals are

Table 4 Reference levels for air kerma–area product and auxiliary reference intervals for fluoro time and number of images for coronary angiography, coronary angiography+intervention, and lower limb arteriography, and entrance surface air kerma (ESAK) rate in fluoro and cine mode

Procedure	Reference level	Reference intervals			
	Kerma–area product, Gy cm^2	Fluoroscopy time, min	Number of images	ESAK rate (fluoro), mGy min^{-1}	ESAK rate (cine), mGy min^{-1}
CA	40	3.8–6.5	530–650	14–26	96–240
CA+PCI	140	8.9–18.1	1272–1610		
LLA	45	1.9–3.0	120–270		

CA coronary angiography, *CA + PCI* coronary angiography + intervention, *LLA* lower limb arteriography

Table 5 Reference levels for P_{KA} (Gy cm^2), for lower limb arteriography (LLA), coronary angiography (CA) and combined cardiac procedure (CA+PCI), reported in the literature

Procedure	This work	Vano et al. 1995 [19]	Ruiz Cruces et al. [18]	Holm and Leitz [14]	Neofotistou et al. [20]	Veit and Bauer [21]	Hart et al. [13]	Aroua et al. [17]	Balter et al. [15]	Bleeser et al. [22]	D'Helft et al. [16]	Padovani et al. [12]	Vano et al. 2008 [11]
CA	40	69		80	57	60	29	80	50		42	45	
CA+PCI	140							260					
LLA	45	88	36			85	36	210		75			100

proposed for these parameters as well (also presented in Table 4). The intervals are set for ESAK rates measured with a 20-cm PMMA phantom, at a FoV of approximately 25 cm, in the routinely used fluoroscopy and cine mode.

As insufficient data on cumulative dose were collected, no reference levels were proposed for this quantity. However, studies should continue to aim to collect more information about this parameter in view of proposing a reference level in the future.

The purpose of the proposed reference levels for P_{KA} is to serve as a trigger for further investigation into the practice; the auxiliary intervals are intended to aid this investigation in order to identify the possible cause(s) of a potentially increased patient dose. For example, if the assessment of typical patient doses in a given department yields an average P_{KA} value that is greater than the reference level, this should trigger an investigation into the practice to determine which parameters might be in need of optimisation. The ESAK rates in different fluoro modes and the ESAK value for the cine modes can be assessed at this point and compared with the auxiliary intervals. If these are exceeded, this might point to the need to optimise the settings of the angiography equipment used.

The P_{KA} reference levels are not to be compared with the patient exposure from individual cases; a large enough sample of procedures should be pooled and analysed, the mean value of which should be compared with the reference values.

The reference levels for P_{KA} during coronary angiography, reported in literature, ranged from 29 Gy cm^2 [13] to 80 Gy cm^2 [13, 14], with an average value of 57 Gy cm^2. The reference level for P_{KA} proposed in the present study is in agreement with most of the results reported during recent years [11, 13, 15, 16].

The comparison of the reference level proposed in this study for the combined cardiac procedure (CA+PCI) with data in the literature was hindered by the fact that almost all reference sources provided values either for the angioplasty procedure (PTCA) or for percutaneous coronary intervention (PCI) and only one of them [15] had a reference value for a combined CA+PCI procedure.

Reference levels reported for lower limb arteriography exhibit greater variance, the maximum difference reaching as high as a factor of 6 [13, 17, 18]. The reference level proposed here is comparable to only a few of the published results [13, 18].

Conclusion

The recently concluded national study on patient exposure in interventional diagnostic and therapeutic procedures performed in Bulgaria revealed variations in the type, age and technical conditions of the angiography equipment used throughout the country. Substantial differences were observed in the protocols and exposure parameters used for the procedures, as well as in the technical adjustments of the angiography units. Logically, these differences result in variations in the mean patient dose (measured in terms of the air kerma–area product), the mean fluoro time and also the entrance surface air kerma rate in fluoroscopy and acquisition modes.

There is an apparent necessity for improvement in the classification of peripheral interventional procedures and for a unification and standardisation of the applied protocols. Efforts should be invested in order to increase the radiation protection awareness of interventional medical specialists.

It is important that patient doses are routinely recorded and compared with the reference levels in view of the optimisation of the procedures. The most practical quantity to record in interventional procedures is the air kerma–area product. Cumulative dose is also useful; however, more data should be collected and further studies should be performed in order to establish the relationship between cumulative dose and the maximum skin dose. Reference levels (P_{KA}) and auxiliary reference intervals (*FT, N, and ESAK*) were proposed for three selected interventional procedures (coronary angiography, combined coronary procedure and lower limb arteriography).

Acknowledgements The study was partially conducted under the SENTINEL EU Coordinated Action Project, IAEA Regional Project R9/093 and Finland–Bulgaria PHARE Twinning Project BG 2006/IB/SO 01.

The authors would like to thank the medical staff at all the departments visited for their cooperation in the data collection for the study.

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