

Interventional Cardiology-Eight Years of Practice: Do Increased Experience and Technological Evolution Lead to Undertaking More Difficult Cases and Higher Patient Doses?

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Abstract

In our dedicated catheterization laboratory, within the years 2009–2016, 8286 Interventional Cardiology (IC) procedures were performed by two interventional cardiologists with more than 10 years of experience. There were 5469 Coronary Angiographies (CA) and 2817 Percutaneous Coronary Interventions (PCI). The purpose was to analyze annual patient radiation data, investigate trends and compare with national and international literature and Dose Reference Levels (DRL). Patient doses were determined in terms of: kerma-area product P_{KA} , fluoroscopy time FT and reference air-kerma K_{ar} . Concerning the number of frames F, in 1.8% of CA cases and in 40% of PCI cases, was higher than Greek DRLs. P_{KA} , in 13% of CA cases and in 31% of PCI cases, was higher than Greek DRLs. In 0.4% of CA cases, the calculated effective dose values were higher than 40 mSv, whereas in 0.9% PCI cases higher than 80 mSv. In 0.2% of CA cases, PSD was higher than 2 Gy and in 0.04% cases higher than 3 Gy. In 13% of PCI cases, PSD was higher than 2 Gy, in 3% higher than 3 Gy and in 0.4% higher than 5 Gy. FT in 19.2% of CA cases and in 32% of PCI cases was higher than Greek DRLs. The radiation dose trends in IC procedures in this hospital, for the last 8 years, suggest that patient radiation doses in CA are less variable through the years compared to PCI. Doses are comparable to the literature and median values are lower than Greek and European DRLs. The practice of the well experienced interventionalists, with the support of evolving technology, shows that simpler procedures, like CA, need slight shorter FT, while the most demanding procedures like PCI, appear to require more frames without increasing in FT or PSD.

Keywords: Interventional Cardiology; Patient dose; Fluoroscopy time; Peak skin dose; Effective dose

Introduction

Several studies have been published, in the field of Interventional Cardiology (IC) procedures, focused on factors that may influence patient radiation exposure [1-10]. Radiation involves a probability of carcinogenic effects (the risk of stochastic effects), the actual probability increasing with the magnitude of the dose. Effective dose (E) is a dose quantity used to roughly estimate the radiogenic risk to an individual (radiation induced cancer is an example). The stochastic risk to an average member of an irradiated population is expressed in terms of sieverts (Sv). Effective dose also enables medical examinations or techniques to be compared in terms of radiation dose.

Radiation also involves detrimental health effect (i.e., skin injury, hair loss, cataracts) for which the severity increases with the dose of radiation. The effect is not observed unless the threshold is exceeded, although the threshold dose is subject to biologic variation [11]. In interventional fluoroscopy procedures, the tissue of concern is the skin, although the lens of the eye is another consideration. The skin at the site where radiation enters the body receives the highest radiation dose of any body tissue. Once the threshold dose is exceeded, the injury becomes progressively more severe with increasing dose, although the true severity of major injuries will only become apparent weeks to months after the procedure. Peak Skin Dose (PSD) is a dose quantity estimating the highest dose at any portion of a patient's skin during a procedure. Peak skin dose includes contributions from both the primary X-ray beam and from scatter. Peak skin dose is measured in grays (to soft tissue).

The prime objective of radiation protection is not only to minimize the stochastic risks but also to avoid deterministic injuries, by keeping radiation dose as low as reasonably achievable. However, the potential risk of patient radiation damage must be viewed in the context of

the general benefit of these procedures and the likelihood of greater trauma associated with heart surgical interventions and perhaps with imminent death if the intervention was not performed. Radiation dose associated with IC procedures is a complex function of a large number of variables including the X-ray tube voltage (kVp) and the product of tube current and exposure time (mAs), the X-ray field size, the number of projections, focus-skin distance as well as practical skill of the operator [12]. Therefore, for optimizing radiation exposure in such procedures, it is essential to measure patient doses in a given set-up of cardiac catheterization laboratory. During IC procedures, both PSD and E need to be determined. However, neither PSD nor E is measured on a routine basis, because the patient dose monitors commonly available to the operator are kerma-area product (P_{KA}), fluoroscopy time (FT) and reference air-kerma (K_{ar}), which can be recorded in real time from the control console of the IC equipment. The kerma-area product, P_{KA} , is defined as the integral of dose across the X-ray beam ($Gy \cdot cm^2$) and provides information about patient dose as well as the irradiated skin area. It is a unit historically known as dose-area product (DAP) and currently named kerma-area product (KAP, current notation P_{KA}). P_{KA} provides a good index for estimating stochastic risk

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but is not directly useful for estimating tissue reactions. It is also a well-accepted dosimetric parameter for comparison between patient doses during different interventional procedures and is also used to assess E [13]. Air Kerma is the energy extracted from an X-ray beam per unit mass of air in a small irradiated air volume. Air kerma is measured in grays. The reference air-kerma ($K_{a,r}$) is the air kerma accumulated at a reference point in space which is located along the central ray of the X-ray beam of the C-arm fluoroscopic system at a distance of 15 cm away from the isocenter toward the X-ray tube focal spot and is provided by the manufacturer. $K_{a,r}$ was introduced by the International Electrotechnical Commission for standardization purposes and is similar to the Cumulative Dose (CD) used in the past [14]. Reference point air kerma does not include backscatter and is measured in grays (Gy). Reference point air kerma is sometimes referred to as reference dose, or cumulative air kerma. FT is required by the US Food and Drug Administration on all fluoroscopy equipment manufactured. However, it lacks information regarding X-ray beam area, thickness of patient and technique employed [15].

It is desirable to measure the PSD to map skin doses in a given IC set-up. However, this does not reflect the entire dose delivered during the course of the procedure. So, the information about the peak as well as overall dose to the patient during IC procedure can be obtained in terms of PSD as well as other dose metrics such as P_{KA} , FT and $K_{a,r}$. Each patient record should contain P_{KA} and/or reference point air kerma ($K_{a,r}$).

The number of fluoroscopy-guided procedures in cardiology is increasing over time, a fact that led European countries to investigate closely this field and to gather information in the attempt to define Dose Reference Levels (DRLs) [16-19]. The concept of DRLs was first introduced by the International Commission on Radiological Protection in Publication 60 [20] and further expanded in Publication 73 [21]. The results of patient dose surveys could then be compared with the corresponding DRL value, to discover which IC departments have doses above the reference values. An audit process could then be initiated to determine the underlying cause of higher doses and an action plan developed to improve radiological techniques for dose reduction purposes. In practice, DRL values may be regarded as an optimization tool for the reduction of patient doses. In order to establish DRLs, the third quartile of value from survey data distribution is calculated. The median values of the distribution must also be assessed in order to estimate the variation in values.

The purpose of this study was to evaluate patient radiation doses during coronary angiography (CA) and Percutaneous Coronary Intervention (PCI) procedures in a dedicated catheterization laboratory and to analyze annual patient radiation data performed the last 8 years, investigate trends and compare with national and international literature and DRL values. The dosimetry approach was to determine patient doses in terms of three dose metrics: P_{KA} , FT and $K_{a,r}$. The PSD was calculated to take into consideration the likelihood of deterministic skin effects and to isolate procedures involving PSDs higher than 2 Gy. Radiation induced skin effects are deterministic in nature, with a generally accepted threshold dose of 2 Gy [11]. A Belgian study has proposed two P_{KA} action levels for skin dose [13,19,22]. A first P_{KA} action level of 125 Gy·cm² corresponds to 2 Gy which is the threshold dose for erythema. A P_{KA} value >125 Gy·cm² would imply an optional radio pathological follow-up depending on the cardiologist's decision. The second action level of 250 Gy·cm² corresponds to 3 Gy skin dose and would imply a systematic follow-up. To cover the stochastic risk associated with IC procedures, the effective dose to patients was also evaluated by using proposed factors for conversion of P_{KA} to E [22].

Materials and Methods

The IC procedures were performed by two interventional cardiologists with more than 10 years of experience. Coronary Angiography (CA) and Percutaneous Coronary Intervention (PCI) were included in the sample. The procedures were carried out with a Philips Integris Allura Xper FD20 fully digital monoplane machine with flat detector (FD) (Philips Medical Systems, Best, The Netherlands) in a C-arm configuration.

The radiation dose for each patient was provided by the X-ray system in terms of kerma-area product (P_{KA}) and reference point air kerma ($K_{a,r}$). Patient radiation metrics in terms of patients age, kerma-area product (P_{KA}) in Gy·cm², reference air-kerma ($K_{a,r}$) in mGy, fluoroscopy time (FT) in min and total number of frames (F) were analyzed from a pool of data ranging from January 2009 to May 2016.

Quality control was also routinely assessed (including kVp, mA, beam quality [Half-Value Layer, [HVL]) assessment, image quality and radiation dose evaluation) as per the Hellenic Quality Control Angiography machine Protocol set by the Greek Atomic Energy Commission [23]. The P_{KA} meter was calibrated against a digital multimeter (Piranha, RTI Electronics, Molndal, Sweden) with a solid-state detector (CB2-11110201) that has calibration traceable to a standard laboratory. As quoted by the manufacturer, the inaccuracy of the instrument in dose measurements is 2.3%. The calibration was made according to the method summarised in 'The National Protocol for Patient Dose Measurements in Diagnostic Radiology' [24], without the table and mattress routinely used.

Conversion factors and equations

Effective dose: Effective dose (E) is estimated by adding the products of the dose in an organ or tissue and the specific weighting factor for that tissue. The weighting factors are values that express the sensitivity of each particular tissue or organ to radiation. Each weighting factor relates to the risk associated with stochastic effects and has specific value for every organ. E is expressed in millisieverts (mSv). In practice, it is very difficult to determine E, since the radiation doses in 12 organs would have to be measured during each cardiological procedure. Therefore, the use of a special conversion factor provides a practical way to estimate E. Modern fluoroscopy machines calculate kerma-area product P_{KA} using generator and collimator settings. P_{KA} does not depend on the distance of the measuring plane from the X-ray source because dose decreases according to the inverse square law and the area of the field increases with the square of the distance. This keeps the P_{KA} value constant at any distance. P_{KA} represents the total energy incident on the patient. P_{KA} is combined with a coefficient depending on the irradiated portion of the body and protocol (irradiated organs) to estimate E. The coefficients range from 0.028 to 0.29 (mSv/Gy·cm²) depending on type of X-ray procedure with regards to the beam geometry and beam quality. They are derived from Monte-Carlo simulations using anthropomorphic digital phantoms. For coronary angiographies, the most recent studies determine E from P_{KA} using a conversion factor of 0.185 mSv/Gy·cm² for normal adult patient, although the precise factor value depended on whether an additional copper filtration was available during cine mode [22].

Peak skin dose: The estimation of absorbed dose at the surface of the skin by fluoroscopy, to account for deterministic effects, is a difficult task since the examination is conducted with changing regularly the incidence X-ray beam. However, it is possible to have an idea of the dose to the skin using a particular operational quantity, called the cumulative dose. This quantity estimates the dose that would have

received the skin if the geometry was kept unchanged throughout the procedure. It may be considered that the cumulative dose indicated by the facility in cardiology in many (but not all cases) overestimates the dose to the skin by a factor of 2-3 since several tube-detector incidences are used that distributes the exposure of the skin. If this operational quantity is not available, the skin dose could be estimated from the P_{KA} [25]. So, kerma-area product P_{KA} correlates with peak skin dose (PSD) as it expresses the total X-ray flux in the beam. Reference point air kerma ($K_{a,r}$) correlates better with peak skin dose (PSD) and possible radiation injuries, as this quantity indicates the cumulative air kerma at the reference point during the procedure. PSD has been implemented as a function of the highest radiation dose at any point of the patient's skin to stand for the likelihood and severity of radiation-induced skin injury to the patient. $K_{a,r}$ is clinically useful as a real-time safety indicator. It does not take into account the scattered radiation and, therefore, is not the actual dose to the patient's skin. For this reason, the latest guidelines of the Society of Interventional Radiology (SIR) Safety and Health Committee presented a conversion formula to help operators estimate the PSD from the $K_{a,r}$ shown on the X-ray machine at the end of interventional procedure [11]:

$$PSD = 206 + 0.513 \times K_{a,r} \text{ (mGy)} \text{ (for } K_{a,r} > 500 \text{ mGy)} \quad (1)$$

It should be underlined that these are broad estimations that on the other hand provide an immediate estimate of patient PSD easily and quickly in every day routine practice. Of course, accurate estimation of PSD must account for gantry motion, patient size and patient location relative to the gantry but is not possible without dedicated expensive software purchased additionally to the angiography machine.

Results

Our data resulted in 8286 IC procedures (diagnostic and therapeutic interventions) within the years 2009–2016. There were 5469 (66%) diagnostic Coronary Angiographies (CA) and 2817 (34%) Percutaneous Coronary Interventions (PCI). The range of kVp used in these procedures was 50–125 kVp. Patient demographic data collected included age (63 ± 12 , 20–92 years), weight (84 ± 18 kgr) and height (168 ± 15 cm). The patient exposure-related parameters recorded for each IC procedure were number of images F, FT, $K_{a,r}$ and P_{KA} , as they are presented in Table 1.

For CA procedures, median values of P_{KA} , $K_{a,r}$, FT, and F ranged from 24.5–30.5 Gy·cm², 365–447 mGy, 2.3–3.6 min and 436–514 respectively. The P_{KA} , $K_{a,r}$ and FT values reached 639 Gy·cm² (Figure 1), 6.8 Gy and 103 min respectively. The max number of frames was 3326. On the other hand, for PCI procedures, median values of P_{KA} , $K_{a,r}$, FT, and F ranged from 86–104 Gy·cm², 1532–1942 mGy, 12.7–14.8 min and 1082–1294 respectively. The P_{KA} values reached 818 Gy·cm² (Figure 2), $K_{a,r}$ max was 13.5 Gy, FT reached 99 min and the max number of frames was 6535. Looking closer to these results, for CA cases, the concentration of higher P_{KA} values is noted to be almost stable over time. On the other hand, for PCI cases, this concentration seems to be increased for the second half of the total number.

PSD value was calculated by applying equation (1). Median PSD ranged from 393 to 435 and from 992 to 1202 mGy for CA and PCI procedures respectively (Table 2). During CA, PSD_{max} was found 5003 mGy (Figure 3), whereas during PCI, PSD_{max} was found 7134 mGy (Figure 4). Looking closer to these results, for CA cases, the concentration of higher PSD values is noted to be almost stable over time. On the other hand, for PCI cases, this concentration seems to be increased for the second half of the total number.

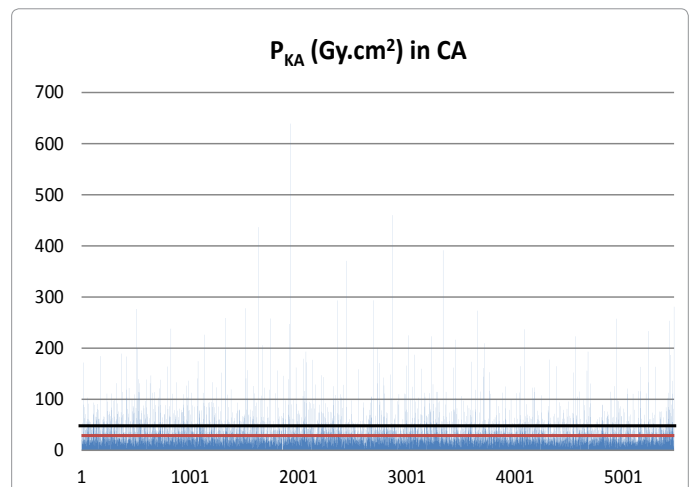


Figure 1: P_{KA} values in Gy·cm² during all CA procedures (5469) from January 2009 to May 2016. Red horizontal line corresponds to 45 Gy·cm² (European DRL) and black horizontal line corresponds to 55 Gy·cm² (Greek DRL).

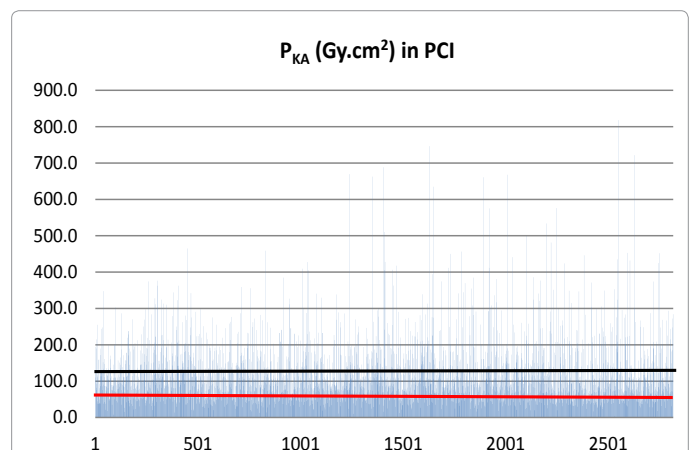


Figure 2: P_{KA} values in Gy·cm² during all PCI procedures (2817) from January 2009 to May 2016. Red horizontal line corresponds to 75 Gy·cm² (European DRL) and black horizontal line corresponds to 130 Gy·cm² (Greek DRL).

The effective dose E was also calculated from the corresponding value of P_{KA} by using the factor 0.185 mSv/Gy·cm², for converting P_{KA} to E [17,21]. Median E effective ranged from 4.5 to 5.7 mSv and from 15.9 to 19.1 mSv for CA and PCI procedures respectively (Table 2). During CA, E_{max} was found 118 mSv (Figure 5), whereas during PCI, E_{max} was found 151 mSv (Figure 6). In Table 2 mean values and SD of F, $K_{a,r}$, PSD, P_{KA} and E, per year, per procedure, are also presented for comparison reasons (Discussion section).

Concerning the number of frames F, for 99 CA cases (1.8%) F value was higher than 1250 (Greek DRL) (Table 3 and Figure 7). Among 2817 PCI cases, 1128 (40%) F value was higher than 1300 (Greek DRL), for 302 cases (11%) F value was higher than 2000 and for 37 cases (1%) F value was higher than 3000 (Table 3 and Figure 7).

Concerning P_{KA} , for 719 CA cases (13%) P_{KA} value was higher than 55 Gy·cm² (Greek DRL) and for 15 cases (0.3%) P_{KA} value was higher than 250 Gy·cm² (Table 3 and Figure 7). Among 2817 PCI cases, 885 (31%) P_{KA} value was higher than 130 Gy·cm² (Greek DRL) and for 172 cases (6%) P_{KA} value was higher than 250 Gy·cm² (Table 3 and Figure 7).

Year	Procedure	No. of patients	No. of frames median	No. of frames 3 rd	No. of frames max	FT median (min)	FT 3 rd (min)	FT max (min)	K _{ar} median (mGy)	K _{ar} 3 rd (mGy)	K _{ar} max mGy	P _{KA} median (Gy·cm ²)	P _{KA} 3 rd (Gy·cm ²)	P _{KA} max (Gy·cm ²)
2009	CA	438	453	639	3326	3.6	7.2	21.3	444	729	3325	27.047	46.537	189.187
	PCI	307	1126	1456	3826	12.7	22	63	1771	2598	12217	97.066	144.695	376.401
2010	CA	523	436	570	1197	3.2	6.4	49	414	617	3549	27.918	425.231	276.474
	PCI	356	1082	1437	3828	13.6	20.2	58	1711	2539	8773	103.709	154.889	464.954
2011	CA	355	446	555	1782	3.3	6.5	28.3	402	615	2212	28.028	44.310	226.154
	PCI	235	1125	1523	3254	13.8	20	68	1532	2295	7290	96.985	138.589	458.816
2012	CA	765	497	607	1633	3.2	5.8	61	409	613	6773	27.764	40.865	639.103
	PCI	386	1167	1578	3960	14.3	21.5	99	1619	2489	11310	93.956	142.866	669.506
2013	CA	906	492	619	2777	3.0	5.1	48	436	624	9351	27.626	40.318	460.071
	PCI	415	1294	1741	4272	14.8	22.8	91	1942	3044	13505	103.011	155.898	746.534
2014	CA	1024	489	635	1762	2.6	4.5	103	417	588	4958	27.296	39.652	391.367
	PCI	430	1242	1644	3026	14	21.7	73	1777	2767	11592	95.336	144.686	667.674
2015	CA	1127	475	648	2295	2	3.8	41	365	565	3432	24.503	38.107	257.393
	PCI	541	1143	1545	6535	13	19.9	94	1577	2676	12593	85.759	142.908	818.086
2016	CA	330	514	678	2178	2.4	4.1	33	447	642	3595	30.523	43.699	280.778
	PCI	148	1194	1591	4105	13.5	20.8	62	1730	2825	10594	93.830	150.277	452.099
All years	CA	5469	475	619	2119	2.9	5.4	48	417	624	4649	27.588	42.001	340.066
	PCI	2817	1172	1564	4101	13.7	21	76	1707	2654	10984	96.206	146.851	581.759

Table 1: Median, 3rd quartile and maximum values for number of frames, FT, K_{ar} and P_{KA}, along with number of patients, per procedure, per year.

Year	Procedure	No. of patients	No. of frames mean	No. of frames SD	K _{ar} mean (mGy)	K _{ar} SD (mGy)	PSD mean (mGy)	PSD SD (mGy)	PSD median (mGy)	P _{KA} mean (Gy·cm ²)	P _{KA} SD (Gy·cm ²)	E mean (mSv)	E SD (mSv)	E median (mSv)
2009	CA	438	542	290	579	407	503	209	434	35.605	26.366	6.59	4.88	5.00
	PCI	307	1202	488	2014	1292	1239	663	1115	111.934	66.582	20.71	12.32	17.96
2010	CA	523	482	179	534	418	480	214	418	36.631	29.673	6.78	5.49	5.16
	PCI	356	1217	544	1981	1248	1222	640	1084	118.187	70.393	21.86	13.02	19.19
2011	CA	355	502	237	508	351	467	180	412	36.211	27.226	6.70	5.04	5.19
	PCI	235	1252	495	1775	1066	1117	547	992	109.021	66.746	20.17	12.35	17.94
2012	CA	765	533	211	528	490	477	251	416	36.955	40.299	6.84	7.46	5.14
	PCI	386	1291	556	1954	1303	1208	668	1037	115.202	75.733	21.31	14.01	17.38
2013	CA	906	541	231	536	496	481	254	430	34.898	32.128	6.46	5.94	5.11
	PCI	415	1450	600	2355	1626	1414	834	1202	124.815	92.835	23.09	17.17	19.06
2014	CA	1024	544	229	511	398	468	204	420	34.435	29.103	6.37	5.38	5.05
	PCI	430	1351	526	2227	1576	1348	808	1118	119.382	89.061	22.09	16.48	17.64
2015	CA	1127	551	255	466	356	445	182	393	31.662	24.488	5.86	4.53	4.53
	PCI	541	1299	654	2140	1677	1304	860	1015	116.334	93.965	21.52	17.38	15.87
2016	CA	330	582	271	542	408	484	209	435	37.881	32.851	7.01	6.08	5.65
	PCI	148	1320	579	2209	1530	1339	785	1093	117.969	76.582	21.82	14.17	17.36
All years	CA	5469	535	238	525	416	475	213	416	35.535	30.267	6.57	5.60	5.03
	PCI	2817	1298	555	2082	1415	1274	726	1082	116.605	78.987	21.6	14.6	17.75

Table 2: Mean values and SD of number of frames, K_{ar}, PSD, P_{KA} and E effective and median values PSD and E, along with number of patients, per procedure, per year.

In accordance with the P_{KA} values, the same shape is followed by the effective dose E values, as can be seen in Figures 5 and 6. It is calculated that 24 CA cases (0.4%) received more than 40 mSv, whereas 25 PCI cases (0.9%) received more than 80 mSv.

Among 5469 CA cases, 11 (0.2%) received PSD higher than 2 Gy and 2 cases (0.04%) received PSD higher than 3 Gy (Table 3 and Figure 7). Among 2817 PCI cases, 357 (13%) received PSD higher than 2 Gy, 97 cases (3%) received PSD higher than 3 Gy and 12 cases (0.4%) received PSD higher than 5 Gy (Table 3 and Figure 7).

Concerning the time FT, for 1049 CA cases (19.2%) FT value was higher than 6 min (Greek DRL) and for 471 CA cases (8.6%) FT value was higher than 10 min (Table 3 and Figure 7). Among 2817 PCI cases, 899 (32%) FT value was higher than 18 min (Greek DRL), for 320 cases (11%) FT value was higher than 30 min and for 137 cases (5%) FT value was higher than 40 min (Table 3 and Figure 7).

Discussion

The mean and 3rd quartile P_{KA} values recorded during both CA and PCI procedures in the present study were compared with those published in the literature (Figures 8 and 9). Mean values for patient doses are not essential, as they do not represent the dominant daily practice in every laboratory. The IC procedures present wide variation in patient dose resulting from complexity. Median and 3rd quartile values have been established as they are identified to be more representative, the radiation dose data being not normally distributed. It can be seen however that in both figures, current study's CA P_{KA} value is lower than half of the presented laboratories, whereas current study's PCI P_{KA} value is the 4th (13 centers) and 3rd (12 centers) higher respectively. It is generally accepted that the large variability in the recorded values of P_{KA}, especially during PCI procedures, is mainly attributed to different levels of procedure complexity, patient thickness and skill of the cardiologist.

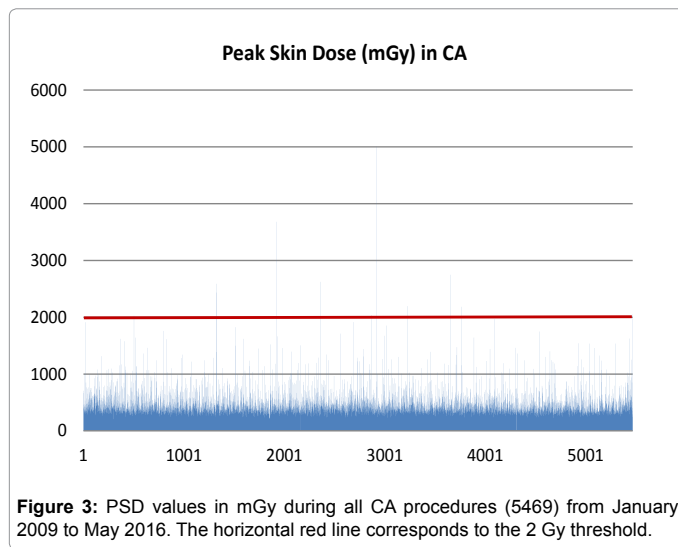


Figure 3: PSD values in mGy during all CA procedures (5469) from January 2009 to May 2016. The horizontal red line corresponds to the 2 Gy threshold.

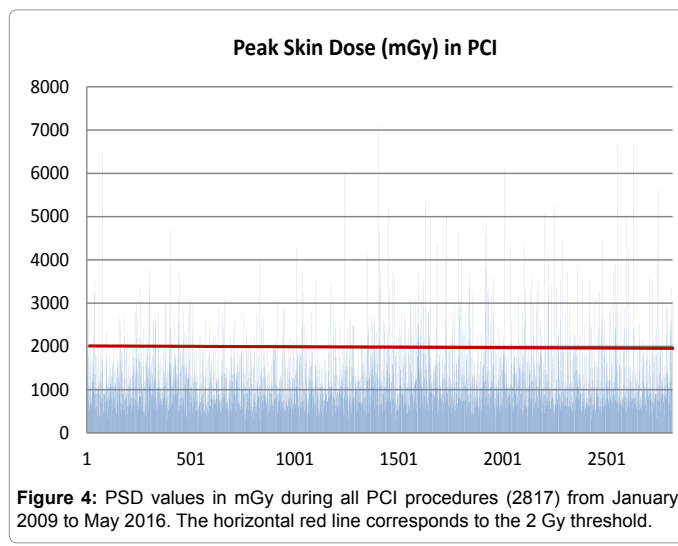


Figure 4: PSD values in mGy during all PCI procedures (2817) from January 2009 to May 2016. The horizontal red line corresponds to the 2 Gy threshold.

	2009	Percentages (%)						
		2010	2011	2012	2013	2014	2015	2016
Frames_CA>1250	2.7	0	2	1.4	1.4	2	3	3
Frames_PCI>1300	34.5	33	37	39	50	47	37	42
Frames_PCI>2000	4.9	8.7	8	10	15	12	12	14
Frames_PCI>3000	0.7	0.8	0.4	0.8	2	0.5	3	0.7
P _{KA} _CA (Gy.cm ²)>55	17.5	17	0	15	13	11	11	13
P _{KA} _CA (Gy.cm ²)>100	2.7	4	0	4	3.4	3	2	4.6
P _{KA} _PCI (Gy.cm ²)>130	30	36	30	30	35	32	28	31
P _{KA} _PCI (Gy.cm ²)>200	9	12.6	8.5	12	13	11	15	13
P _{KA} _PCI (Gy.cm ²)>300	2.3	2.2	1.3	3	4	5	5	2
PSD_CA (Gy)>2	0	0.2	0.4	0.4	0.4	0.3	0	0.3
PSD_PCI (Gy)>2	8.8	11	6	10	18	14	15	13.5
PSD_PCI (Gy)>3	2.3	1.7	0.9	2	4	5	5	4.7
FTime_CA (min)>6	22	27	27	24	23	16.5	12	14
FTime_CA (min)>10	10	12	14	10.7	10.6	7	5	5.5
FTime_PCI (min)>18	23	29	31	37	38	34	30	32
FTime_PCI (min)>30	8.5	9	8.5	12	14	13	12	11
FTime_PCI (min)>40	2.3	2.8	2.6	6	6	7	6	3

Table 3: Percentages (%) of higher values for (number of) frames, P_{KA}, PSD and fluoroscopy time FT per year, per procedure type. Bold numbers correspond to the Greek DRLs.

Concerning mean effective dose, for CA procedures current study has the 4th higher value (8 centers) and for PCI procedures it has the 2nd higher value (Figure 10). It has to be highlighted however that slight differences were noticed between the values of conversion factor calculated by Uniyal et al. [4] and Betsou et al., which were 0.183 mSv/Gy.cm². Nevertheless, although E is derived from P_{KA} by using a single multiplicative factor, it provides a convenient way to judge patient doses [26-35].

Concerning mean PSD value, for CA procedures current study has the 2nd higher value (7 centers) and for PCI procedures it has the 3rd higher value (Figure 11). Although the mean PSD (median values are even lower) for CA and PCI procedures in this study were well below the deterministic threshold of skin injury, 13%, 3% and 0.4% of patients received PSDs during PCI exceeding 2, 3 and 5 Gy, respectively (Table 3 and Figure 7). Dose Reference Levels are the guide to what is achievable with current good practice, rather than optimum performance, and are dose neither limits nor thresholds that define competent performance of the operator or the equipment. A mean dose for a procedure that is less than the RL does not guarantee that the procedure is being performed optimally. On the other hand, even with optimal technique,

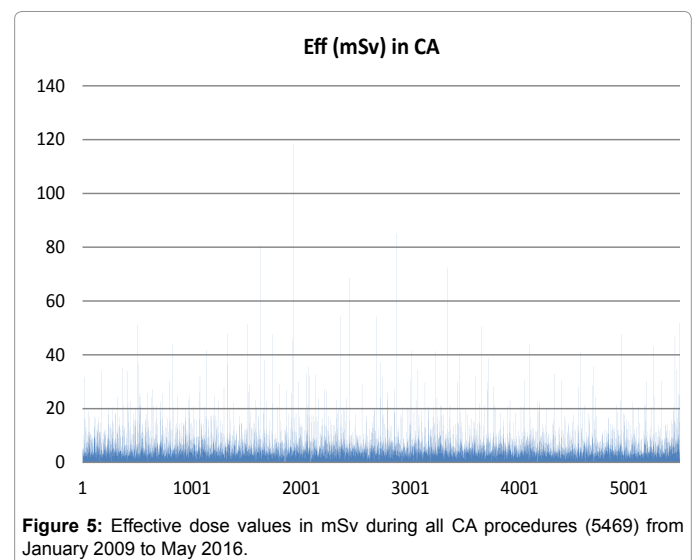


Figure 5: Effective dose values in mSv during all CA procedures (5469) from January 2009 to May 2016.

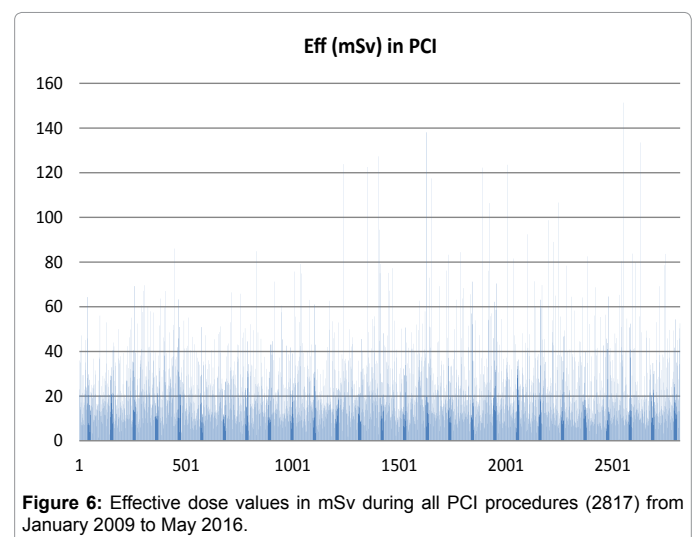


Figure 6: Effective dose values in mSv during all PCI procedures (2817) from January 2009 to May 2016.

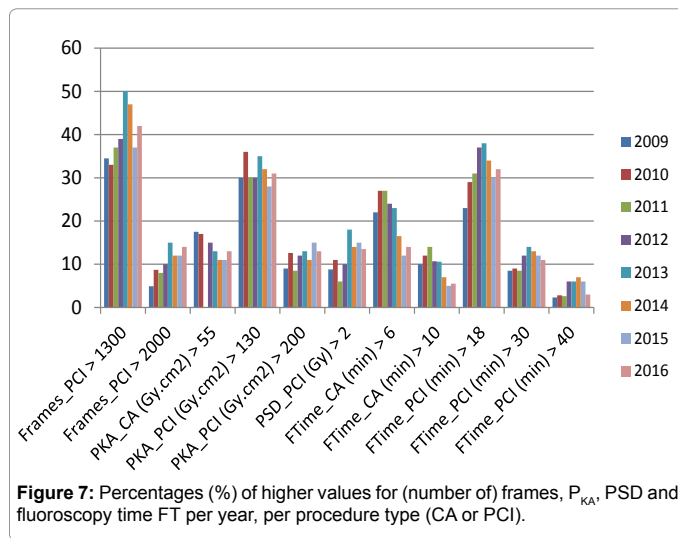


Figure 7: Percentages (%) of higher values for (number of) frames, P_{KA}, PSD and fluoroscopy time FT per year, per procedure type (CA or PCI).

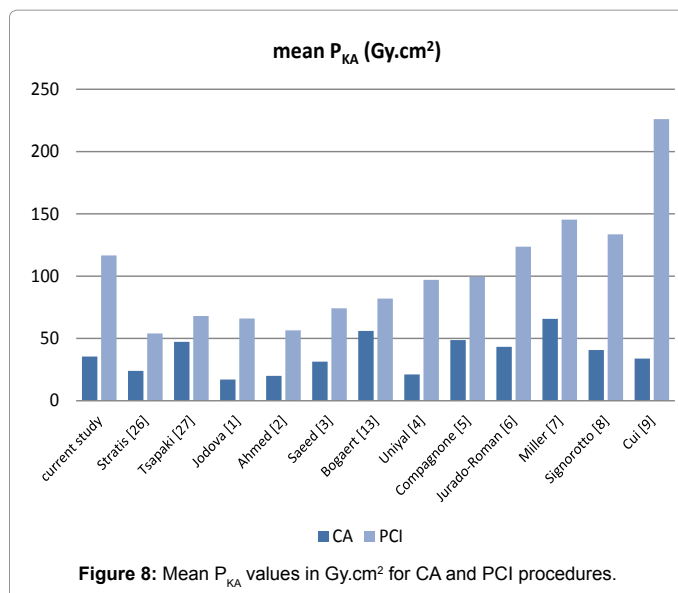


Figure 8: Mean P_{KA} values in Gy.cm² for CA and PCI procedures.

it is not always possible to keep peak skin dose below the threshold for skin effects. This does not necessarily indicate poor operator technique. It is not necessarily a contraindication to performing or continuing a procedure. However, no deterministic injury was reported from any patient during these eight years of practice in this unit. An event that can be explained by the fact that interventionists are well trained and have always in mind to move the X-ray source as often as possible, so as none patient small skin region to receive large portion of the incident radiation. Nevertheless, the operator is always notified when a significant radiation dose has been administered. The patients are also instructed to notify the operator if any signs or symptoms of a possible radiogenic deterministic effect are observed. The operator writes an appropriate note in the patient's medical record. Follow-up of patients who have received a significant radiation dose applies at 10–14 days and 1 month after the procedure, according to the guidelines [11].

The everyday practice of the two well-experienced interventionists, with the help of evolving technology, shows that simpler procedures, like CA, need slight shorter fluoroscopy time, while the most demanding procedures like PCI, appear to require more frames without increasing in fluoroscopy time or patient's skin dose.

Conclusion

The data of this study resulted in 8286 IC procedures within the years 2009–2016. There were 5469 (66%) Coronary Angiographies (CA) and 2817 (34%) Percutaneous Coronary Interventions (PCI). Concerning the number of frames F, for 99 CA cases (1.8%) F value was higher than 1250 (Greek DRL). Among PCI cases, 1128 (40%) F value was higher than 1300 (Greek DRL), for 302 cases (11%) F value was higher than 2000 and for 37 cases (1%) F value was higher than 3000.

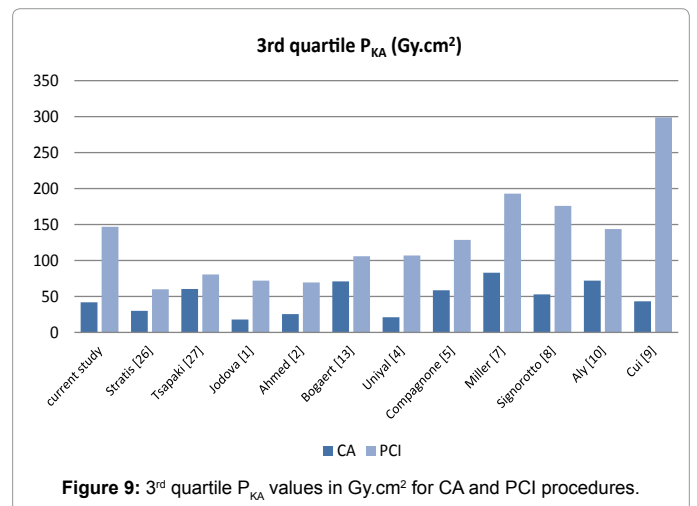


Figure 9: 3rd quartile P_{KA} values in Gy.cm² for CA and PCI procedures.

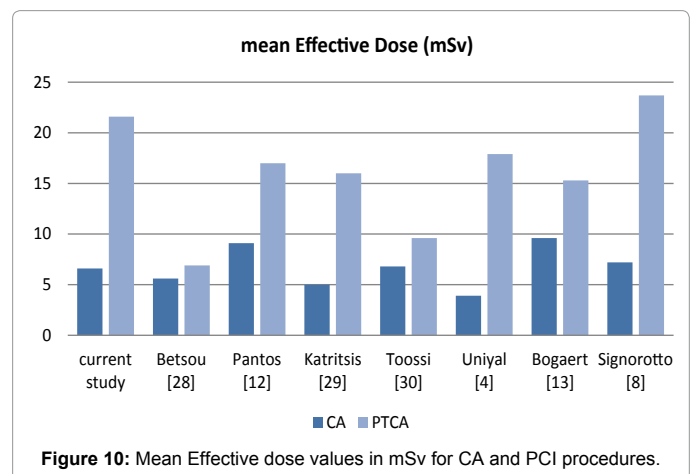


Figure 10: Mean Effective dose values in mSv for CA and PCI procedures.

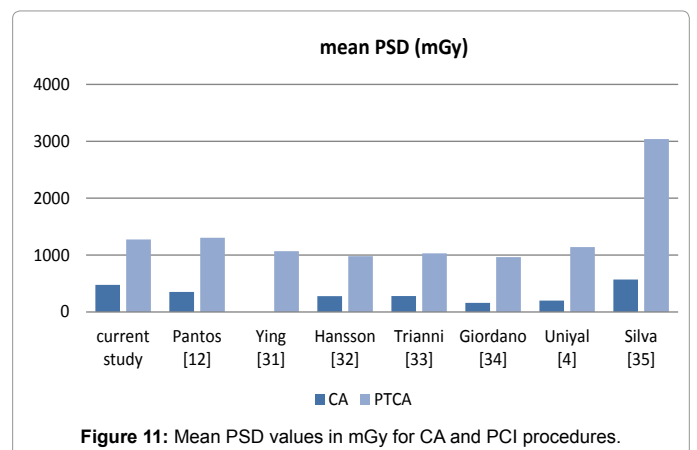


Figure 11: Mean PSD values in mGy for CA and PCI procedures.

Concerning P_{KA} for 719 CA cases (13%) P_{KA} value was higher than 55 Gy·cm² (Greek DRL) and for 15 cases (0.3%) P_{KA} value was higher than 250 Gy·cm². Among PCI cases, 885 (31%) P_{KA} value was higher than 130 Gy·cm² (Greek DRL) and for 172 cases (6%) P_{KA} value was higher than 250 Gy·cm². The calculated effective dose values showed that in 24 CA cases (0.4%) patients received more than 40 mSv, whereas in 25 PCI cases (0.9%) they received more than 80 mSv. Among the CA cases, 11 (0.2%) received PSD higher than 2 Gy and 2 cases (0.04%) received PSD higher than 3 Gy. Among the PCI cases, 357 (13%) received PSD higher than 2 Gy, 97 cases (3%) received PSD higher than 3 Gy and 12 cases (0.4%) received PSD higher than 5 Gy. Concerning the fluoroscopy time (FT), for 1049 CA cases (19.2%) FT value was higher than 6 min (Greek DRL) and for 471 CA cases (8.6%) FT value was higher than 10 min. Among the PCI cases, 899 (32%) FT value was higher than 18 min (Greek DRL), for 320 cases (11%) FT value was higher than 30 min and for 137 cases (5%) FT value was higher than 40 min. The radiation dose trends in IC procedures in the hospital of this study for the last 8 years suggest that patient radiation doses in CA are less variable through the years compared to PCI. Doses are comparable to the literature and median values are lower than Greek and European DRLs. Even with optimal technique, it is not always possible to keep patient radiation dose below the threshold for skin effects. However, no deterministic injury was reported from any patient during these eight years of practice in this unit, while the appropriate actions and the recommended follow-up of patients who have received a significant radiation dose were strictly followed.

The daily practice of two well-experienced interventionists, with the help of evolving technology, shows that simpler procedures, like CA, need slight shorter fluoroscopy time, while the most demanding procedures like PCI, and appear to require more frames without increasing in fluoroscopy time or patient's skin dose.

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