Original Research

Patient Dose in Cardiac Radiology

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Introduction: In diagnostic and interventional cardiology procedures performed with the use of X-ray diagnostic imaging systems, the long fluoroscopy time and the large number of cine projections, as well as the repetition of the procedure due to the recurrence of the lesion—a common event—result in a high locally delivered skin dose, which may even lead to patient skin necrosis. The purpose of this study was to collect information in order to estimate the patient dose during coronary angiography and coronary angioplasty procedures, using the dose-area product measuring system of the X-ray angiographic machine.

Methods: Dose-area product (DAP), fluoroscopy time, number of sequences and frames per sequence were collected for each of 108 coronary angiography and 101 coronary angioplasty procedures, using the dedicated X-ray machine of the hospital's haemodynamic department, where more than 3000 procedures are performed per year.

Results: The median values of DAP were 19.96 and 40.17 Gy.cm^2 for coronary angiography and angioplasty, respectively; fluoroscopy times were 7.7 and 23.4 minutes; and the numbers of frames were 457 and 641, respectively. There was a strong correlation between DAP and fluoroscopy time, the number of frames per sequence, and hence the cine recording time.

Conclusions: The entrance skin dose delivered to the patient in the haemodynamic department was lower than that of other studies, although the mean fluoroscopy time per patient was longer. The practices in use satisfy the diagnostic reference levels as far as DAP values and number of frames per patient are concerned, but not with regard to fluoroscopy time. We did not find the correlation between doctors' experience and DAP values reported in other studies, as we did not take into account the complexity index of the lesion.

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There are many reports in the literature of cases where patients suffered radiation skin lesions, even necrosis, after interventional cardiology procedures during which the radiation dose delivered during fluoroscopy and cinematography exceeded the threshold of deterministic skin effects (dose threshold 2-6 Gy for erythema, 3 Gy for hair loss, 18 Gy for necrosis).[1,2] The dose value and any consequent radiation-related complications are related to many factors. Fat patients receive a higher dose, since the automatic exposure control system increases the functional parameters of the tube and hence radiation output in order to achieve satisfactory imaging. The complexity of the individual lesion and the ability of the invasive cardiologist to perform fine manipulation of the catheter in the region of interest also affect the total exposure time, which is directly proportional to the patient radiation dose. The imaging technique (patient focus distance, image intensifier field size, X-ray field size, low fluoro pulse rate, short cine recording time, low cine frame rate, etc.) also determines the patient's skin dose.

The physical quantity with the greatest interest in the radiation protection of patients undergoing invasive cardiological

procedures is the entrance skin dose, since the patient's skin, more than any other tissue, will be exposed to the radiation. The physical quantity dose-area product (DAP) determines patient dose, and provides information about the irradiated skin surface area. The skin dose can be extracted from DAP if the irradiated skin surface area is known; conversely, the dimensions of the field can be determined if the skin dose is known. The skin dose may also be determined indirectly from a meter placed in the exit of the X-ray tube, provided the X-ray focus to skin distance is known. However, during an examination the focus to skin distance changes, as do the size of the X-ray field and the image intensifier magnification, making it difficult to measure or even estimate the dose. Another way of measuring the patient's dose is by placing thermoluminescent dosimeters (TLDs) or film (or both) in the region where the X-ray beam enters the patient's body.[3] The simultaneous use of TLDs and film allows accurate measurements with information about the distribution of the dose on the skin, but it is a time-consuming and costly technique. Thus, the measurement of DAP was the method of choice for patient dosimetry in the present study since it allows a fast and reliable estimation of the patient's skin dose.

Based on studies that investigated the relationship between DAP and entrance dose measured with film and TLDs, and on proposed factors for the conversion of DAP to effective dose, we also evaluated the effective dose received by patients in the haemodynamics laboratory and hence the stochastic risk of the procedure (i.e. possibility of carcinogenesis).[4]

Methods

The study was carried out from March to July 2007 and included 209 patients, 108 of whom underwent coronary angiography and 101 balloon angioplasty with stenting in one or more coronary stenoses. In all cases the radiological device used was the Innova 2000 (General Electric, Milwaukee WI, USA), which is under maintenance contract with the manufacturer and the supplier and which also undergoes a regular quality control by the medical physics staff of the hospital to ensure safe use. From the quality control measurements it was determined that the dose per frame during cine recording was stable for the same measurement conditions and was in accordance with the requirements of the relevant authority (the Greek Atomic Energy Commission), namely a maximum fluoro patient entrance dose rate at the interventional reference point (IRP: 15 cm from the isocentre towards the X-ray tube) <100 mGy/min. Measurements were made using a Solidose 400 electrometer (S/N 4110) with an R-100 X-ray beam detector (RTI Electronics, Flojelbergsgatan, Mondal, Sweden) calibrated in a standards laboratory. The angiographic unit is equipped with a flat panel imaging detector (General Electric Apollo™, Milwaukee WI, USA) with an amorphous Silicon photo diode array, which is always positioned above the examination table and offers a choice of four imaging fields of dimensions 20×20, 17×17, 15×15 and 12×12 cm. In addition, the unit is capable of performing low and standard dose fluoroscopy, with 15 or 30 pulses per second, and an image acquisition rate of 15 or 30 frames per second. In practice, "low dose" (15 pulses per second) fluoroscopy is used, while the image acquisition rate is 15 frames per second. kV and mA in both fluoroscopy and cine mode are regulated by an automatic exposure control system. The angiographic unit is equipped with a patient dose measuring system placed in front of the X-ray tube (Diamentor M4 KDK, PTW Freiburg GmbH, Germany). This meter consists of a flat ionisation chamber measuring DAP in $cGy.cm^2$ and an ionisation chamber calibrated to measure the entrance skin dose (in mGy) at the centre of the radiation field and at 70 cm from the focus of the X-ray tube. The measurement accuracy is 10.5%. The DAP meter software also records the total exposure time (fluoroscopy and cine in seconds), as well as the radiation area (in cm^2) in a plane perpendicular to the radiological beam and at a distance of 70 cm from the focus of the X-ray tube.

For each examination we recorded the following: DAP value; fluoroscopy time; dose and field size at 70 cm (the average position of the examination table) from the tube focus; and the number of sequences and cine frames per sequence. The patient's sex was recorded, as was the name of the physician who performed the examination. All procedures were carried out by invasive cardiologists of the hospital.

According to the recommendations of the International Commission on Radiological Protection (ICRP), the risk of fatal carcinogenesis attributable to exposure to total-body irradiation is 5% Sv^{-1}.[5] Betsou et al calculated a coefficient for converting DAP to effective dose (0.183 $mSv.Gy^{-1}.cm^{-1}$) after measurements on a anthropomorphic phantom using TLDs and DAP meter under common interventional cardiological practice conditions.[4] The use of this coefficient introduces uncertainties with respect to the correlation between the position and size of the various

Table 1. Dose rate during fluoroscopy (fluor.) and dose per frame during cine recording for four fields of the flat imaging system.

Size of imaging system field (cm^2)	kV fluor.	mA fluor.	Fluor. dose rate (mGy/min) at IRP	kV cine	mA cine	Dose per frame (μGy) at IRP
20 × 20	86	7	25.0	74	28	173
17 × 17	89	7.1	32.6	77	47	282
15 × 15	98	7.3	42.0	87	37	311
12 × 12	108	6.9	48.0	104	32	380

IRP – interventional reference point.

organs in the phantom and those in the real human body undergoing examination, or the number and type of radiological projections or the kV used under real examination conditions as opposed to the conditions in the Betsou experiment. There is also the question of the real dose value that is measured by TLD devices. However, the use of the conversion coefficient provides a means for a close approximation to the risk arising from the invasive cardiological procedures.

Results

The entrance dose rate (pulsed fluoroscopy, "low dose", 15 pulses/s) in a water phantom 20 cm thick, placed on the patient table at 15 cm from the isocentre towards tube side (IRP), with the flat panel imaging system at 5 cm above the phantom, is given in Table 1. It represents the typical dose which is delivered in the posterior-anterior projection to a normal-sized patient by the angiographic unit under normal fluoroscopy. The same table also shows the corresponding dose-per-frame values during cinematography.

Table 2 shows the mean values of DAP for coronary angiographies and angioplasties for men and women. Statistical analysis of the DAP measurements revealed that they were not normally distributed. Thus, apart from mean values and standard deviations (SD), the median and 75th percentile values were also calculated in order to give a better picture of the distribution (Table 3).

Table 2. Mean value of dose-area product (DAP) in men and women during coronary angiography and angioplasty.

Sex	No.	%	DAP ($Gy.cm^2$)
Angiography:			
Women	22	20	19.35
Men	86	80	25.21
Angioplasty:			
Women	30	30	48.47
Men	71	70	53.17

By multiplying the mean DAP values by the coefficient converting DAP measurements to effective dose, we calculated the mean effective dose received by the patients of this study. This was 4.3 mSv for coronary angiography and 9.85 mSv for angioplasty, while the mean risk of developing fatal cancers due to radiation was 0.02% for coronary angiography and 0.05% for angioplasty—much lower than the risk of the procedure in itself.

We also checked for any correlation between DAP and the total time of irradiation, the fluoroscopy time, and the number of cine frames. As shown in Figures 1-3, as expected there was a strong positive correlation ($p<0.0001$), despite the fact that, apart from the above three parameters, the total dose received by a patient also depends on other factors.

All the procedures were carried out by the six invasive cardiologists of the haemodynamic laboratory. We investigated the correlation of DAP, fluoroscopy time, and the number of cine frames, with the work experience of the invasive cardiologist expressed in years. The raw data are summarised in Table 4. The statistical analysis did not show any correlation between the above parameters and the doctor's level of experience.

Table 5 shows total DAP dose from all procedures (angiographies and angioplasties) performed by each cardiologist, as well as the cardiologist's personal dosimeter dose during the study period. The cardiologist's personal dose is recorded by two personal dosimeters provided by the Greek Atomic Energy Commission, one of which is worn on the left shoulder outside the radiology apron, and the other in the region of the genital organs inside the apron. When the dosimeter was worn outside the radiology apron there was a correlation between the patient's dose and the physician's personal dosimeter dose ($p<0.05$). However, the dosimeters worn inside the

Table 3. Statistical parameters of dose distribution, time, and field, during coronary angiography and angioplasty.

	Min	Max	Mean	SD	Median	75th percentile
Angiography:						
DAP (Gy.cm^2)	4	102	24	17	20	30
Fluoroscopy time (s)	75	4484	711	726	462	888
Cine frames	157	1780	493	223	457	600
Area of radiological field 70 cm from focus (cm^2)	105	172	133	15	134	144
Mean entry dose (Gy)	0.029	0.640	0.160	0.117	0.133	0.196
Angioplasty:						
DAP (Gy.cm^2)	9	332	54	47	40	60
Fluoroscopy time (s)	145	6425	1720	1184	1405	2156
Cine frames	207	2125	733	341	641	902
Area of radiological field 70 cm from focus (cm^2)	101	185	133	14	134	144
Mean entry dose (Gy)	0.057	1.134	0.333	0.220	0.266	0.384

DAP – dose-area product.

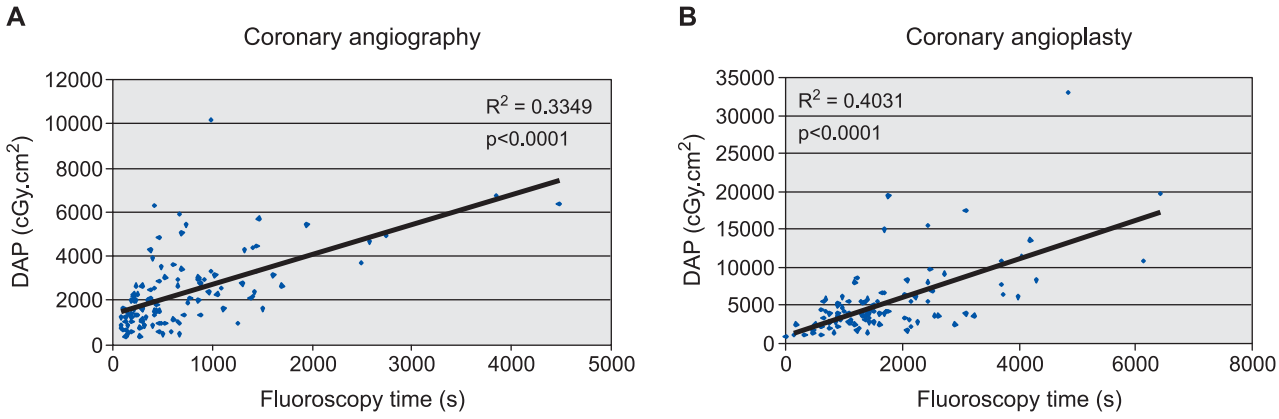

Figure 1. Correlation between dose-area product (DAP) and fluoroscopy time during coronary angiography (A) and angioplasty (B).

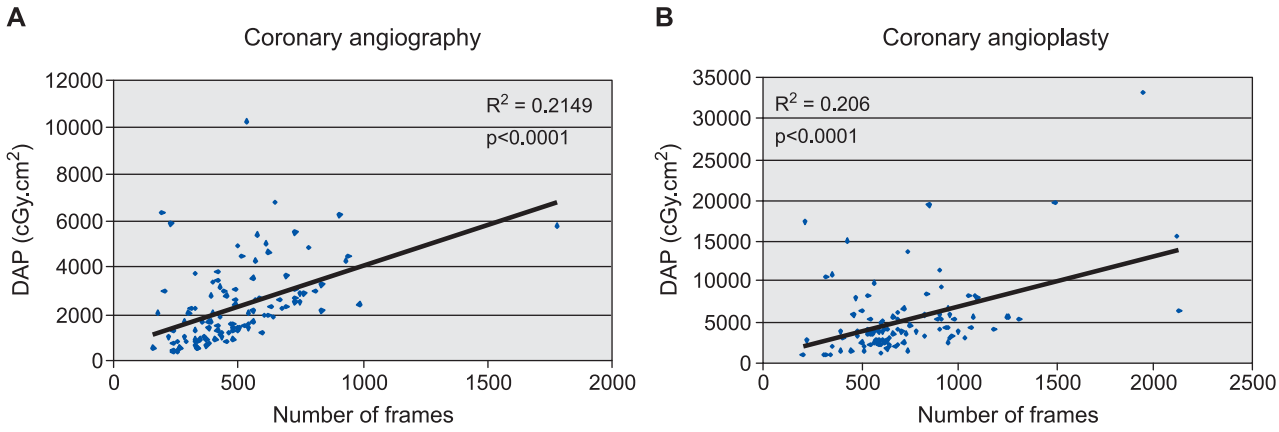

Figure 2. Correlation between dose-area product (DAP) and number of cine frames during coronary angiography (A) and angioplasty (B).

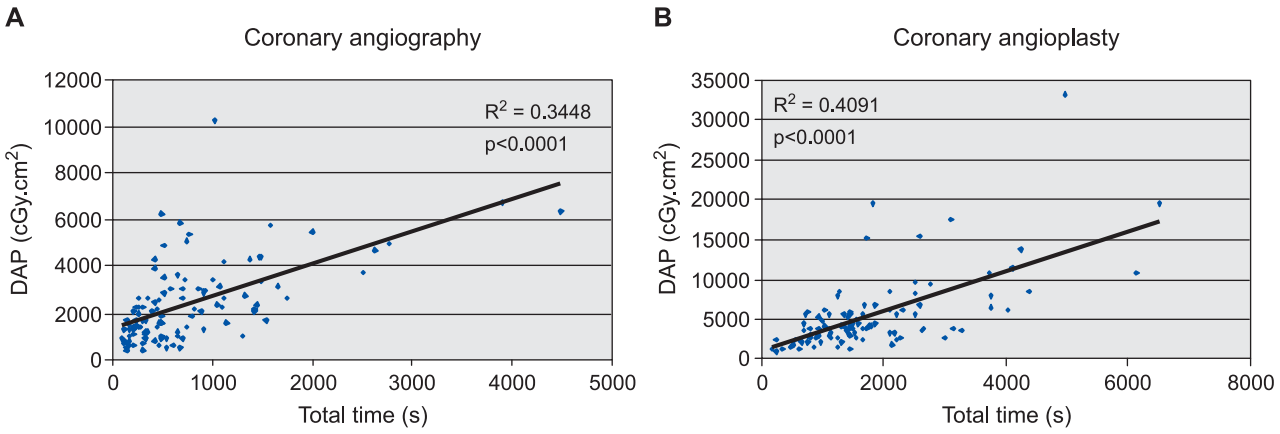

Figure 3. Correlation between dose-area product (DAP) and total procedure time during coronary angiography (A) and angioplasty (B).

apron always show zero readings. These results are similar to those of Tsapaki et al, who found a weak correlation between DAP and physicians' shoulder and foot doses, for both coronary angiography and angioplasty.[6]

Discussion

In recent years, invasive radiology has developed rapidly in terms of both equipment (catheters, drugs, stents, radiology equipment, imaging detectors, etc.) and techniques for accessing even the most remote parts of the human body.[7,8] Invasive procedures are now quite usual in medical practice: 70,000 invasive procedures in the coronary and peripheral vessels are performed per year in Greece (data from the Greek Atomic Energy Commission) and the rate is increasing. Over the last 5 years, our hospital's haemodynamics laboratory has performed an average of 2150 coronary angiographies and 910 invasive procedures per year, while the annual rate has increased by 11% and 22%, respectively.

However, invasive radiology is associated with high patient entrance doses, depending on the degree of difficulty in accessing the point of interest (vessel tortuosity, number of treated vessels) and hence the fluoroscopy time, the patient's size and weight, the use of radiological equipment that does not meet the radiation protection rules, and the interventional cardiologist's insufficient knowledge or inexperience to access and treat the disease (e.g. initial positioning of the patient close to the X-ray tube, use of a high-dose

Table 4. Work experience of the invasive cardiologist and mean values of fluoroscopy parameters during coronary angiography and angioplasty. (The roman numerals I-VI denote the six cardiologists in order of experience, with I being the most experienced and VI the least.)

Experience level	No. of patients	DAP (Gy.cm^2)	Fluoroscopy time (min)	Frames	Cine time (min)	Field (cm^2)
Angiography:						
I	4	30.26	19.4	613	0.68	178
II	10	18.18	7.6	338	0.38	180
III	19	17.74	13.7	371	0.41	173
IV	33	23.25	10.0	614	0.68	164
V	15	27.66	13.7	372	0.41	203
VI	27	26.75	9.9	536	0.60	189
Angioplasty:						
I	7	59.76	52.4	594	0.66	175
II	18	51.73	23.2	571	0.63	170
III	16	29.01	30.3	697	0.77	173
IV	14	37.89	19.8	887	0.99	164
V	17	60.21	27.8	762	0.85	194
VI	29	71.31	30.3	795	0.88	188

DAP – dose-area product.

Table 5. Relation between total dose as measured by dose-area product (DAP) from all cases and operator dose for each cardiologist. (The roman numerals I-VI denote the six cardiologists in order of experience, with I being the most experienced and VI the least.)

Cardiologist	Total DAP dose for all cases (Gy.cm^2)	Operator dose (mSv) for dosimeter	
		outside apron	inside apron
I	539	0.30	/
II	1113	1.39	/
III	992	2.45	0.00
IV	1048	2.30	0.00
V	1438	1.80	/
VI	2790	4.64	0.00

fluoroscopy mode with a high pulse rate for a long time, clumsy manoeuvres, exposure of the same skin region during the procedure, use of a large radiation field, etc.). Taking into account that some patients are likely to undergo invasive treatment two or three times in the near future, because of disease recurrence at the same or a different location, the limits of skin tolerance to radiation may be exceeded, resulting in lesions.[9] It should be noted that the occurrence or not of skin damage due to radiation also depends on the time interval between two or more procedures carried out in the same region.

The measurement and recording of total fluoroscopy time and a patient skin dose index for invasive cardiological procedures have been adopted for years in most countries having category I provision of healthcare services according to the United Nations. This practice, as well as the maximum permitted patient entrance dose rate levels for coronary angiography units, have been embodied in Greek and European legislation, in order to set an upper limit on the dose rate to which the patient is exposed.[10-12] For this reason also all modern coronary angiographs are equipped with at least one device that measures the dose multiplied by the irradiated surface (DAP meter).

In the present study we recorded data from a total of 209 patients, 157 men and 52 women. These numbers reflect the higher risk that men have of developing coronary artery disease.[13-14] Given that men tend to weigh more, the higher DAP values for men shown in table 2 for all kinds of radiological examination are to be expected.

The results of this study are compared with those from the international literature in Tables 6 and 7.[15-20] Although the mean fluoroscopy time in our patients was longer than in the other studies—more than double—the DAP values are lower, for both angiography and angioplasty. The lower DAP values are due to the smaller number of cine frames recorded than in any of the other studies, except that of Broadhead et al.[18] The effect of the cine recording on the total patient dose can be seen in Table 4. Physician III, though having a long fluoroscopy time during coronary angiographies, has a relatively low DAP value because of the low number of cine frames recorded. The largest DAP value was recorded for physician I, who had the longest fluoroscopy time and a long cine time. However, there are many factors that affect the final value of DAP, apart from the fluoroscopy time and the number of cine frames. In Table 4, physicians III and VI, though performing angioplasties with similar fluoroscopy times, have significantly different DAP values. This may be due to differences in the technique used (e.g. diaphragm closing).

We found no correlation between the cardiologist's work experience and the patient dose. This is in conflict with the study of Tsapaki et al, who found that DAP values, fluoroscopy time, and the number of cine frames reduce as the physician's experience increase, for cases with the same degree of difficulty.[15] In the present study the degree of difficulty was not recorded and thus could not be included in the analysis. However, it is possible that older doctors recorded higher doses either because they undertook the more difficult cases, or because they are less sensitive to the radiation protection aspect.

Another study attempted to estimate the effect of case complexity and the invasive cardiologist's work experience on the patient dose.[21] A complexity index was calculated in accordance with the criteria of the American Heart Association, which take into account the following: patient age and sex; single or multiple vessel disease; any previous surgical procedures; single or multiple angioplasty; use of single or double catheter; use of bal-

Table 6. Comparison of results from this and other studies of coronary angiography.

Study	Patients	DAP (Gy.cm^2)				Fluoroscopy time (min)	Frames
		Mean	SD	Median	75th percentile	Mean	Mean
This study	108	23.52	16.9	19.96	30.00	11.9	493
Tsapaki[15]	195	47.3	27.9	39.1	60.4	6.5	1779
Vano[16]	288	66.5		45.7	69.3		
Padovani[17]	13	39.3	18			3.6	878
Broadhead[18]	2174	57.8		45.5	69.9	5.7	689
Zorzetto[19]	79	55.9		52.5	65.6	4.9	1350
Delichas[20]	45			69.3			

DAP – dose-area product.

Table 7. Comparison of results from this and other studies of coronary angioplasty.

Study	Patients	DAP (Gy.cm^2)				Fluoroscopy time (min)	Frames
		Mean	SD	Median	75th percentile	Mean	Mean
This study	101	53.82	46.71	40.17	59.99	28.7	733
Tsapaki[15]	97	68	48.7	58.3	80.7	12.2	1914
Vano[16]	45	87.5		66.7	122.3		
Padovani[17]	54	101.9	84.9			18.5	1434
Broadhead[18]	214	77.9		61.1	100.6	12.4	504
Zorzetto[19]	31	91.8		82.6	104.6	12.2	1500
Delichas[20]	37			120.2			

DAP – dose-area product.

loon at one or more points; deployment of one or more stents in bifurcated vessels, etc. The complexity coefficient was found to be strongly correlated with DAP, fluoroscopy time, and the number of cine frames.

Diagnostic reference levels

The diagnostic reference levels (DRLs) for a particular radiological examination or invasive radiological procedure are the levels of dose, or other parameter (e.g. fluoroscopy time, number of cine frames), usually defined in terms of the 75th percentile of the distribution of the parameter in question, that are determined from the study of a large number of patients of typical weight and height who underwent the specific procedure in different diagnostic or therapeutic centres in different countries. The reasoning is that since 75% of medical centres can complete this procedure in an absolutely satisfactory way from the medical point of view, following a protocol that entails a dose below the DRL, then it is reasonable to expect the remaining 25% to modify their protocol in order to keep the patient dose below the level laid down by the DRL. There must be a DRL for every radiological examination, according to EURATOM guideline 97/43, as well as to Greek legislation. DRLs are not restrictive limits, but rather guideline levels whose establishment and application in invasive cardiology must be flexible because of the complexity of these procedures. In the literature there are studies that propose DRL values for invasive cardiological examinations.[22-23] The World Health Organisation suggests that DRLs should be expressed as quantities that are easily measurable, while providing useful information about the patient dose.[24]

Table 8 shows the proposed DRLs for coronary angiography and angioplasty, expressed as DAP values, fluoroscopy time, number of cine frames, as well as the corresponding values from the present study.[22] The 75th percentiles of both DAP values and number of cine frames in our study are lower than the recommended values, for both angiography and angioplasty. However, the fluoroscopy time in both cases is much longer than the recommended time, and its future reduction will entail a further decrease in the radiation dose patients receive.

Table 8. Comparison of our results with the proposed diagnostic reference level values for coronary angiography and angioplasty.

	Neofotistou[22]	This study			
	75th percentile	Mean	Min	Max	75th percentile
Angiography:					
DAP (Gy.cm^2)	67	23.52	3.57	102.09	30.00
Fluoroscopy time (min)	6	11.9	1.3	74.7	14.8
Frames	1600	493	157	1780	600
Angioplasty:					
DAP (Gy.cm^2)	110	53.82	9.34	331.59	59.99
Fluoroscopy time (min)	20	28.7	2.4	107.1	35.9
Frames	1700	733	207	2125	902

DAP – dose-area product.

Patient dose and staff dose

In general, there is a direct relationship between the patient dose and the dose received by the invasive cardiologist, since during the procedure the patient becomes the main source of irradiation of the staff who work in the radiological room close to the patient. A significantly weaker source of irradiation, to which the staff are also exposed, is the radiation leakage from the tube housing. The indicated way of staff protection from these sources of irradiation, one that is strictly followed by all cardiologists in the haemodynamics laboratory, is the use of ceiling-mounted lead glass shields for the protection mainly of the face and chest, curtains hung around the examination table for the protection of the pelvis and thighs, personal lead glasses for eye protection, and of course radioprotective aprons and collars as a second level of protection for the whole body. Because of these well organised radiation protection measures, dosimeters worn outside the apron recorded only small doses, while dosimeters worn under the apron recorded almost zero radiation.

The invasive cardiologist may reduce the radiation exposure, not only to himself but to his patient as well, by following basic methods such as: a reduction of beam-on time, an increase in distance from the irradiating patient, and the use of shielding between patient and physician. The beam-on time may be reduced by avoiding pointless cine recording; by pausing the fluoroscopy and "freezing" the image; by using pulsed fluoroscopy or cine recordings with a low pulse rate (6 pulses per second if possible, but certainly no more than 12-15 pulses per second); by keeping in mind the five- and ten-minute warning sounds provided by the angiographic machine; and by adequate preparation before the examination. A fourfold drop in the radiation exposure may be achieved by increasing the distance from the patient by one step. During oblique and lateral projections the physician should avoid being on the side of the tube, since the dose rate can be reduced by as much as fivefold by standing on the side of the image intensifier. In addition, the physician can minimise hand exposure by avoiding placing them close to or within the region where the primary beam meets the patient's body. A large reduction in the radiation exposure of the patient and, to a lesser degree, of the invasive cardiologist, along with an improvement in image quality, can be achieved by holding the image intensifier closer to the patient and the tube further away. If the image quality is optimum, the patient's exposure may be reduced by avoiding using any magnified field size of the image intensifier. Large-angle projections (e.g. LAO 50^o with 30^o cranial tilt) are associated with an increase in patient exposure, and hence cardiologist exposure, since the system increases the X-ray output in order to compensate for the greater absorption. Finally, a practical rule for reducing patient exposure and improving image quality is to align the beam limitation device with the boundaries of the image intensifier, restricting the primary beam to the region of interest only.

Conclusions

This study aimed to evaluate the patient's radiation dose during coronary angiography and angioplasty procedures in a large Athens hospital and to compare it with other studies. There is a strong correlation between DAP and the fluoroscopy time, the number of cine frames, and thus the cine recording time. In this study the entrance skin dose on the patients' posterior chest wall was less than in similar studies from oth-

er haemodynamics laboratories in Greece and other European countries. The mean fluoroscopy time per patient was longer than in other studies, whereas DAP was smaller, as a consequence of the smaller number of cine frames recorded. As far as the proposed DRLs are concerned, some parameters were within the limits (DAP, number of frames per patient) while others were not (fluoroscopy time). Contrary to other studies, the work experience of the physician did not show any correlation with DAP, probably due to the case complexity factor, which was not taken into consideration in our analysis.

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