Radiation Protection Dosimetry (2008), Vol. 129, No. 1–3, pp. 39–45
Advance Access publication 20 February 2008
doi:10.1093/rpd/ncn024

INVITED PAPER

PATIENT DOSE IN INTERVENTIONAL RADIOLOGY: A EUROPEAN SURVEY

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Patient doses for a few common fluoroscopy-guided procedures in interventional radiology (IR) (excluding cardiology) were collected from a few radiological departments in 13 European countries. The major aim was to evaluate patient doses for the basis of the reference levels. In total, data for 20 procedures for about 1300 patients were collected. There were many-fold variations in the number of IR equipment and procedures per population, in the entrance dose rates, and in the patient dose data (total dose area product or DAP, fluoroscopy time and number of frames). There was no clear correlation between the total DAP and entrance dose rate, or between the total DAP and fluoroscopy time, indicating that a number of parameters affect the differences. Because of the limited number of patients, preliminary reference levels were proposed only for a few procedures. There is a need to improve the optimisation of IR procedures and their definitions and grouping, in order to account for their different complexities.

INTRODUCTION

Interventional radiological (IR) procedures can give rise to significant radiation dose to patients and can contribute significantly to the total collective dose due to medical exposure, even if their frequency is relatively low. A database on patient doses is a prerequisite for any formulation of national and European guidelines on the optimised use of interventional procedures, including the setting of the reference levels.

In this study, non-cardiac interventional procedures in the sample of hospitals in 20 European partner countries are evaluated. The purpose was 2-fold: to review the current interventional practices and the basic characteristics and performance of interventional X-ray equipment used, and to collect samples of patient doses, both in diagnostic and therapeutic X-ray-image-guided common interventional procedures, in order to assess the possibilities of setting reference levels.

This study has been carried out as a part of the EC-funded SENTINEL project[(1)].

METHODS

The study has mainly been conducted through a questionnaire distributed to all partners. The tabulated forms for the collection of data requested the following information:

- Country data (population, number of X-ray systems used primarily for IR, annual number of diagnostic X-ray procedures and annual number of IR procedures);

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- Data on X-ray systems and their dosimetric characteristics (manufacturer, type, date of the latest quality control, typical entrance dose rate and dose per image, calibration of dose area product or DAP meter);
- Procedures selected (name of the procedure, annual number);
- Patient doses (for each selected procedure): patient data (identification, gender, age, weight, height), total DAP and DAP for fluoroscopy, cumulative dose, fluoroscopy time, number of series and total number of images, complexity of procedure, calibration factors for DAP and cumulative dose.

For patient dose collection, data on four selected common IR procedures, two diagnostics IR and two therapeutic IR procedures, were requested for at least 10 patients per procedure. The IR procedures to be included were characterised as *fluoroscopy guided procedures of catheter insertion.* Lower-limb arteriography and hepatic chemoembolisation were requested to be included if possible. It was assumed that, generally, the partners could provide data for a minimum of two rooms in a selected hospital of the partner's country.

RESULTS AND DISCUSSION

Number of IR equipment and procedures

The number of X-ray equipment (systems) dedicated to IR procedures and the annual numbers of diagnostic and therapeutic IR procedures, all data given per number of population, are shown for a few partners in Figures 1 and 2.

The number of IR systems seems to be between 1 and 5 per one million of inhabitants. The annual number of all IR procedures (non-cardiac) varies from 3500 to 9300 per one million of inhabitants. A majority of the IR procedures seem to be diagnostic. These figures should be considered only illustrative, as the sample of countries is small and there is an inherent large uncertainty of consistent classification of IR procedures and of the dedication of X-ray equipment to IR procedures.

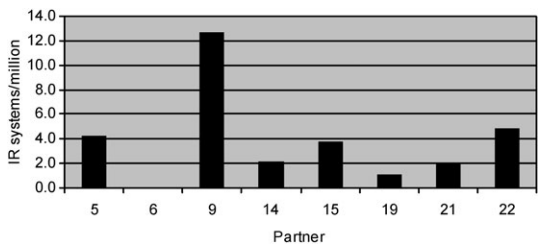

Figure 1. Number of IR systems per number of population.

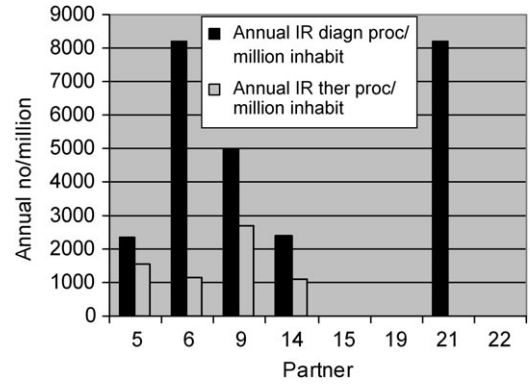

Figure 2. Annual numbers of IR procedures per number of population.

Technical and dosimetric data on IR equipment

Types of IR equipment

Altogether, 28 different types of X-ray equipment from five different manufacturers (General Electric, Philips, Shimadzu, Siemens and Toshiba) were used in this study. About half of the equipment has been installed before 2000, half in the last 6 y.

For patient protection, all systems were provided by the DAP meter, at least occasionally. The cumulative dose indicator was reported only for 3 out of the 28 units. The dose reduction system was reported for 10 out of the 28 units, including pulsed fluoro mode, selection of frame rates and factors to vary dose (seven units), added filtration (five units) and one special system (Siemens C.A.R.E system). Accordingly, except for the DAP meter, the provisions and practices for patient protection seem to vary much.

The acquired images were available in DICOM format on CD for 21 out of the 28 units. The date of the latest quality control testing was reported for 19 out of the 28 units, the date being less than 4-y old in all cases.

Calibration of DAP meters

The calibration of the DAP meter was reported for 15 out of 28 units. The latest calibration was less than 2-y old for all units where it was specified. The calibration factors varied from 0.37 to 1.41 with a mean of 0.83 for 15 units (Figure 3). The results indicate that without taking the calibration factor into consideration, the DAP values indicated will overestimate the true DAP on the average by about 20%. The patient dose (DAP values) presented in this report are corrected for DAP calibration.

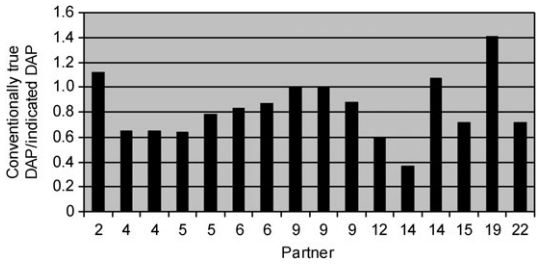

Figure 3. DAP calibration factors for 16 different units from 11 countries.

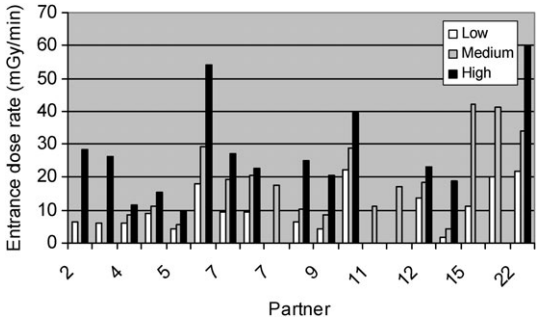

Figure 4. Entrance dose rate in different fluoro modes (low, medium and high) for the IR units considered in this study.

Entrance dose and dose rate

The entrance dose rate reported for the three fluoro modes—low, medium and high—is summarised in Figure 4. The entrance dose rate varies by a factor of 6–14 within a given dose rate setting (fluoro mode). Most of the values in medium or high mode agree reasonably well with the average values from 20 to 42 mGy min^{-1} reported for IR equipment in different IR procedures by Aroua *et al.*[2]

The entrance dose per image reported for two image acquisition modes, low and normal, is summarised in Figure 5. The entrance dose varies by a factor of 100 at maximum. Again, most of the values in the normal mode agree reasonably well with the average values from 1.6 to 6.0 mGy per frame reported for IR equipment in different IR procedures by Aroua *et al.*[2]

Patient doses

IR procedures selected

As could be expected, the four most common procedures selected by each partner were not the same. In total, the patient dose data for 20 different IR procedures were reported. The number of patients

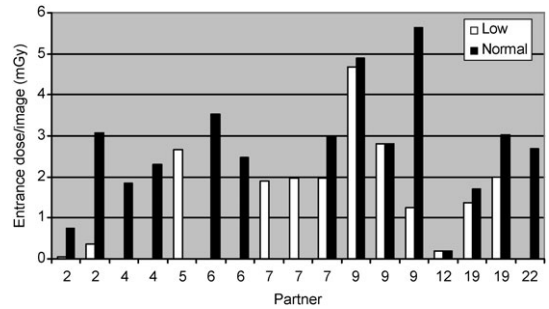

Figure 5. Entrance dose in different image acquisition modes (low and normal) for the IR units considered in this study.

varied between 2 and 434 for these procedures. In total, data for 1343 patients were accepted for consideration. There was no exact consistency of the terms for the different IR procedures, but the partners used different names for practically the same procedures.

For two diagnostic and two therapeutic IR procedures, a reasonable number of patients were received from at least five partners. Further, one diagnostic and one therapeutic procedure had a reasonable number of patients, for which comparative data from other studies were also available. These procedures were as follows and were considered in more detail.

- lower limb angiography (434 patients, 12 partners);
- carotid angiography (112 patients, eight partners);
- cerebral arteriography (72 patients, three partners);
- hepatic embolisation (149 patients, eight partners);
- peripheral therapeutic procedures (142 patients, five partners);
- nephrostomy (49 patients, two partners).

Patient dose values

The summary of the third quartile values calculated from all data in this study are shown in Tables 1–3, for total DAP, fluoroscopy time and number of frames (images), respectively. For comparison, a few other published data have been collected in the tables. To get an impression on the significance of the data, the sample size (number of patients) is shown in parentheses whenever given in the publications.

As an example of detailed data, Figure 6 illustrates the differences of the mean and median values of total DAP between the partners for lower-limb angiography, and Figure 7 illustrates the same for fluoroscopy time. The differences between partners (hospitals) for both DAP and fluoroscopy time are about 5-fold at maximum. At a given hospital, the

Table 1. Total DAP, Gy cm^2, third quartile (3rd Q) values.

IR procedure	This work	Aroua *et al.*[2]	Brambilla *et al.*[3]	Veit and Bauer[4]	Miller *et al.*[5]	Hart *et al.*[6]	Hart and Wall[7]	McParland[8]	Ruiz Cruces *et al.*[9]	Vano *et al.*[10]
Cerebral angiography	107 (72)	125 (91)	198					82.5 (28)		82.8
Carotid angiography	122 (112)							66.3 (11)		
Lower-limb angiography	68 (434)	210 (94)		85		33		103 (15)	36 (35)	87.9
Hepatic embolisation	121 (149)	620 (70)			353		32.5 (6089)			
Nephrostomy	18 (49)					18.9 (274)		62.7 (35)	73 (54)	
Peripheral	31 (142)									

Table 2. Fluoroscopy time (Ft), third quartile values.

IR procedure	This work	Aroua *et al.*[2]	Hart *et al.*[6]	McParland[8]
Cerebral angiography	12 (72)	15 (91)		14.2 (28)
Carotid angiography	11.2 (112)			14.0 (11)
Lower-limb angiography	3.8 (434)	8 (94)	5.1 (5866)	12.5 (15)
Hepatic embolisation	24.3 (149)	30 (70)		
Nephrostomy	15 (18)		8.9 (273)	10.5 (35)
Peripheral	15.1 (142)			

Table 3. Number of frames, third quartile values.

IR procedure	This work	Aroua *et al.*[2]
Cerebral angiography	550 (72)	480 (91)
Carotid angiography	297 (112)	
Lower-limb angiography	285 (434)	150 (94)
Hepatic embolisation	85 (149)	160 (70)
Nephrostomy		
Peripheral	166 (142)	

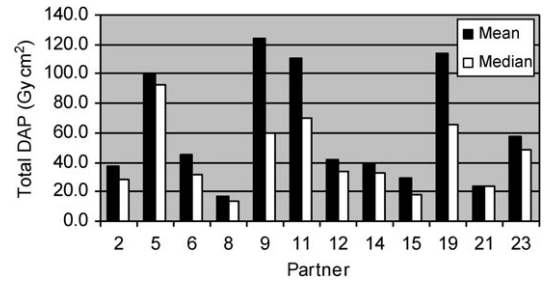

Figure 6. Mean and median values of total DAP for lower limb angiography.

variation of DAP from patient to patient is also very high, and the standard deviation from 20 to 130%.

There is a poor correlation between the total DAP value and the fluoroscopy time as shown in Figure 8. High values of total DAP can be obtained with relatively small fluoroscopy time, suggesting considerable differences in the field size or other parameters of the practices. It has been shown[8,9] that the DAP for fluoroscopy usually is from about one-third to half of the total DAP (from two-thirds to half for radiography), and the high variation of relative amount of fluoroscopy with regard to radiography may also explain the poor correlation in Figure 8. The variations of entrance dose rate of the IR

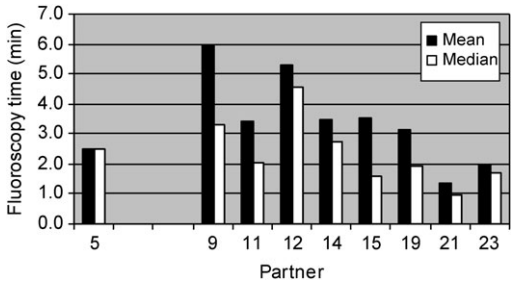

Figure 7. Mean and median values of fluoroscopy time for lower limb angiography.

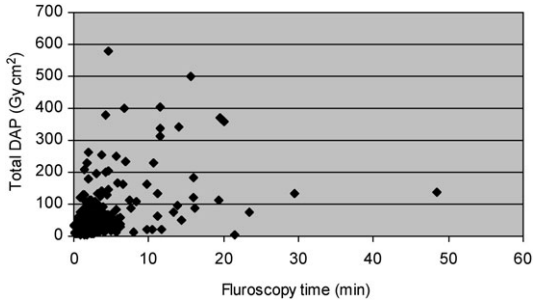

Figure 8. Correlation between the total DAP and the fluoroscopy time (mean values) for lower limb angiography.

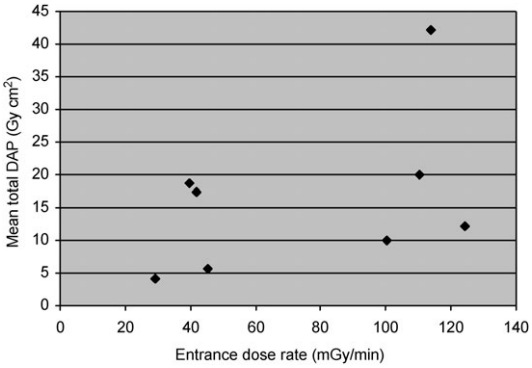

Figure 9. Correlation of the mean of the total DAP values with entrance dose rate as reported by the partners for lower limb angiography.

equipment can explain part of the differences. However, there is no systematic correlation between the total DAP and the entrance dose rate (Figure 9), confirming that there are also other factors influencing the dose differences.

The histogram for the DAP values is shown in Figure 10. The distribution is skewed or characterised by an asymmetric shape: a main peak, a tail and a few extreme values. The histogram is typical

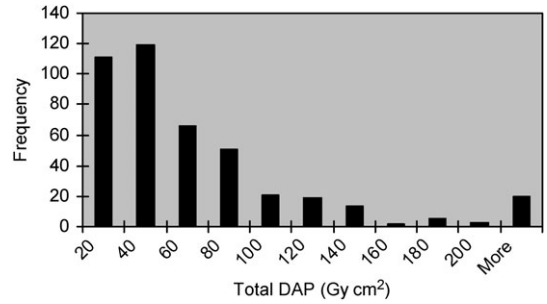

Figure 10. Histogram of total DAP values based on data from all partners for lower limb angiography.

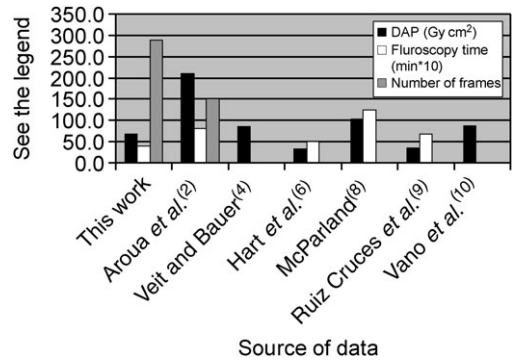

Figure 11. Comparison of the third quartile values obtained in this study with other published values, for lower limb angiography.

of what is expected for examinations involving fluoroscopy.

The third quartile values calculated from all results in this study are compared with other published values in Tables 1–3 and in Figure 11, for DAP, fluoroscopy time and number of frames. Except for the results of Aroua *et al.*,[2] the values obtained in this study agree with other results within about a factor of 3.

For carotid angiography, the differences between the partners (hospitals) for total DAP values were more than 10-fold at maximum, and for fluoroscopy time, about 4-fold. For hepatic chemoembolisation, the differences between the partners for both DAP and fluoroscopy were about 6-fold at maximum. For peripheral therapeutic procedures, the differences between partners for total DAP were over 10-fold, and for fluoroscopy, about 2-fold at maximum.

Reference levels

One of the aims of this study was to obtain insight in the patient dose level in interventional

diagnostic and therapeutic procedures, in order to propose the reference levels. The term 'reference level' is used here instead of 'diagnostic reference level (DRL)', because not only diagnostic but also therapeutic interventional procedures are discussed. Reference levels can be set for total DAP, fluoroscopy time and the number of frames and are intended to be a simple indication of abnormally high values. They act as a trigger to identify those practices in most urgent need of investigation and corrective action, if they cannot be clinically justified.

Preliminary reference levels for a few IR procedures, where a reasonable amount of data from a number of partners in this study was obtained, and also comparative data from other publications were available, are proposed in Table 4. These reference levels should be considered very cautiously and only as the first approximation when better values based on a large number of local or national data are not available. They should trigger *particular attention* to the procedures but might not indicate a proper triggering level for remedial actions applicable to the local conditions of patient doses. This is because of the high variations (up to 10-fold) between the third quartile values from different partners as shown earlier.

The use of reference levels in IR procedures is challenging also because of the high individual variability of the procedures within the same type of procedure. Generally, data from a large number (>50) of patients should be collected and the mean value calculated for comparison with the reference level.

Table 4. Preliminary reference levels for a few IR procedures based on the results of this study.

IR procedure	Reference level		
	Total DAP, Gy cm^2	Fluoroscopy time, min	Number of frames
Diagnostic procedures			
Cerebral angiography	120	15	500
Carotid angiography	120	12	300
Lower-limb angiography	100	5	300
Therapeutic procedures			
Hepatic embolisation	150	30	100
Nephrostomy	20	15	
Peripheral therapeutic procedures	40	15	200

For more reliable setting of reference levels, the definitions and grouping of the procedures should be improved and considerably more data for any given procedure should be collected. When the data come from a number of hospitals, ideally the same number of procedures should be obtained from each partner. The main reasons for high (many-fold) observed differences between the data from different partners should be carefully investigated before they are accepted for calculation of reference levels. This is done to avoid biasing of the results by very abnormal or even erroneous values, representing, that is, very old equipment or some clear shortcoming of practices. For grouping of the IR procedures, the procedures which are reasonably similar from point of view of patient dose values should be identified and classified with appropriate terms.

CONCLUSIONS

There are high variations in the number of IR equipment and the number of IR procedures per population in different European countries. For IR equipment, the variation in entrance dose rate can vary by a factor of more than 10 within a given dose rate setting. For patient dose estimation with DAP values, the DAP values indicated can overestimate the true DAP on the average by 20% unless the calibration factor of the DAP meter is taken into consideration.

The patient dose data collected in this study, that is, total DAP, fluoroscopy time and number of frames, for a number of diagnostic and therapeutic IR procedures, indicated many-fold variations between the mean and median values obtained from several partners. At a given hospital, the variation of total DAP from patient to patient was also very high (standard deviation 20–130%). There was no clear correlation between the total DAP and the entrance dose rate, or between the total DAP and the fluoroscopy time, indicating that there are a number of parameters of the procedures affecting the dose differences.

Because of the limited number of patients, preliminary reference levels have been proposed only for a few procedures, where a reasonable amount of patients from several partners was available and where also comparisons with other published data could be made. These levels should be used very cautiously as the first approximation until reference levels based on significant amount of national or local data are available.

There is a clear need to improve the optimisation of IR procedures. Further, for setting the reference levels, the definitions of procedures and their proper grouping with regard to the patient doses should be developed, whereby the different complexities of the procedures should also be considered.

FUNDING

This study is part of the SENTINEL project and has been co-funded by the European Commission under the European Research and Training Programme on Nuclear Energy within the Sixth Framework Programme (2002-2006).

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