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AN AUDIT OF DIAGNOSTIC REFERENCE LEVELS IN INTERVENTIONAL CARDIOLOGY AND RADIOLOGY: ARE THERE DIFFERENCES BETWEEN ACADEMIC AND NON-ACADEMIC CENTRES?

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A wide variation in patient exposure has been observed in interventional radiology and cardiology. The purpose of this study was to investigate the patient dose from fluoroscopy-guided procedures performed in non-academic centres when compared with academic centres. Four procedures (coronary angiography, percutaneous coronary intervention, angiography of the lower limbs and percutaneous transluminal angioplasty of the lower limbs) were evaluated. Data on the dose–area product, fluoroscopy time and number of images for 1000 procedures were obtained from 23 non-academic centres and compared with data from 5 academic centres. No differences were found for cardiology procedures performed in non-academic centres versus academic ones. However, significantly lower doses were delivered to patients for procedures of the lower limbs when they were performed in non-academic centres. This may be due to more complex procedures performed in the academic centres. Comparison between the centres showed a great variation in the patient dose for these lower limb procedures.

INTRODUCTION

The number of percutaneous interventional procedures performed under fluoroscopic guidance has increased in recent years. Cases treated previously with open surgery are now managed by fluoroscopically X-ray-guided procedures. These procedures, however, are associated with significantly high doses to patients. The effective dose may reach 100 mSv while the skin dose may be as high as 20 Gy, resulting in serious radiation-induced skin injuries[1].

Reference levels (RLs) were introduced by the International Commission on Radiological Protection[2] in 1996 and are now widely accepted as a dose management tool for X-ray examinations. The definition and implementation of RLs are straightforward in the case of well-defined examinations, where standard protocols are used, such as in radiography and computed tomography procedures. For procedures involving fluoroscopy, however, establishing RLs is challenging as the variability of fluoroscopy time and the number of images acquired by different operators during these procedures lead to a wide distribution of dose. Patient exposure is related to several factors such as equipment settings, the complexity of the examination, patient anatomy and the experience of the operator.

In recent years, effort has been directed towards defining RLs in fluoroscopy-guided procedures in order to minimise the exposure. Several studies have been published on RLs and patient doses in interventional procedures[3–7]. Given the variability in measured patient exposure, there may be differences between highly specialised and general departments engaged with interventional programmes. To date there has been no systematic investigation of patient doses in non-academic centres. The aims of this study therefore were to: (i) establish the distributions of the dose–area product (DAP), fluoroscopy time (T) and number of images obtained during procedures (n) for non-academic centres, (ii) compare the patient dose delivered in non-academic centres with that delivered in academic ones and (iii) compare the 75th percentile (pctile) values for non-academic centres with the national RLs in Switzerland[7].

METHODS

Thirty-two non-academic centres were invited to participate in a survey about defining RLs in interventional cardiology and radiology. These centres were selected taking into account parameters such as the existence of a local DAP meter, the number of examinations performed in a 3-month period, the balance between the different specialties (interventional radiology and cardiology) and the geographical distribution within the country. The non-academic centres were compared with five academic centres using historical controls (1-y-old). Four procedures were selected for investigation: coronary angiography (CA), percutaneous coronary intervention (PCI), angiography of the lower limbs (AngioLL) and percutaneous transluminal angioplasty of the lower limbs (PTALL). A brief description of these procedures is given in Table 1.

Centres were asked to provide data for at least 15 cases for each procedure. The data collected included patient demographics (age, weight and height), DAP, T and n. Since it is recommended to collect data from average-sized patients[2] (height: 1.70 m and weight: 65–75 kg) and since, for the examinations performed to the trunk of the patient, the dose delivered depends more on the patient diameter rather than the patient weight[8], a simple method to correct the DAP values collected was employed[9]. Assuming that the trunk of the patient is a cylinder, its diameter (d) can be estimated as a function of the height (H), the weight (W) of the patient and the average density of the human body (ρ):

$$d = 2 \cdot \sqrt{\frac{W}{H \cdot \pi \cdot \rho}},$$

where W and H are the weight (in g) and the height (in cm) of the patient, respectively, and ρ is 1 g cm^{-3}. The DAP value was multiplied by the F factor for CA and PCI procedures.

$$F = \frac{\mathrm{DAP}m}{\mathrm{DAP}a} = e^{\mu \cdot (d_m - d_a)},$$

Here, m corresponds to the medium-sized patient and a to the actual patient, μ is the mean attenuation coefficient, 0.3 cm^{-1} for water at 30 keV, d_m is the trunk diameter of the medium-sized patient (height: 1.70 m and weight: 70 kg) and d_a is the trunk diameter of the actual patient.

All units were characterised in terms of image quality and patient dose. The dose measurements were performed using an 11-cm^3 ionisation chamber connected to a Radcal 3036 dosemeter (Radcal Corporation, Monrovia, CA, USA). The entrance skin dose was determined using a 20-cm thick polymethyl methacrylate phantom. The source-to-skin distance and the source-to-detector distance were fixed at 70 and 100 cm, respectively. Image quality was determined, establishing the spatial resolution limit in the centre of a Leeds TOR (CDR) Test Object (Leeds Test Object Ltd, Faxil, Leeds, UK). Each fluoroscopy unit was characterised in terms of the dose rate, dose per frame, image quality index and spatial resolution for three imaging modes (radiography, fluoroscopy and cine-radiography). The output of an image intensifier (II) as opposed to a flat-panel (FP) detector was recorded and taken into account during data analysis. To compare the different DAP meters and obtain a reference point for the dose, the DAP meters were checked using an external reference DAP meter placed over the measuring device of the fluoroscopy unit.

The distributions of the DAP, T and n and the corresponding 75th pctile were established for the non-academic centres. The mean values of the DAP, T and n were determined for the comparison between the centres as well as for the comparison of these centres with the national RLs. For statistical analysis, the Mann–Whitney U test (M–W test) was used to compare any differences between groups. A p-value equal or less than 0.05 was considered statistically significant. Statistical analysis was performed using the SPSS 15 software (SPSS Inc., Chicago, IL, USA).

RESULTS

The survey was conducted over 2 y. The DAP meters were checked before the start and at the end of the survey and were found to be accurate to within 10 %. All local DAP meters, apart from two cases, recorded doses comparable with those

Table 1. Description of the four procedures included in the study.

Type of procedure	Code	Description
Coronary angiography	CA	Examination of the coronary circulation
Percutaneous coronary intervention	PCI	Balloon-dilatation of one or several coronary arteries whether followed or not by stent placement
Angiography of the lower limbs	AngioLL	Examination of the of abdominal aorta, renal arteries and the lower limbs circulation
Percutaneous transluminal angioplasty of the lower limbs	PTALL	Balloon dilatation of lower limb arteries whether followed or not by stent placement

obtained using the external reference DAP meter within the limits set by the Swiss Ordinance on X-ray Units (±30 %). The two DAP meters that were found outside these limits were excluded from the study. Fifty-four fluoroscopy units operating in the participating centres were characterised. Units equipped with an II accounted for 66 % of the total, while units with an FP detector for 34 % of the included hospitals. For CA and PCI procedures, an M–W test showed no significant difference in the DAP between procedures performed with II or FP detectors. Only a small number of AngioLL and PTALL procedures were performed with units equipped with an FP detector, and thus did not allow statistical analysis. The image quality results are not presented as they were outside the scope of this study.

Of the 32 non-academic centres investigated, only 23 centres completed the survey. Centres that completed the survey but provided data for <15 procedures were included only in the final analysis. In total, data from 1002 cases were collected (from both non-academic and academic centres). There were no significant differences between patient age and habitus in the two types of centre. The number of cases, mean values, ranges and 75th pctile values for DAP, T and n for the four procedures are presented in Table 2. For the non-academic centres, the distributions of DAP, T and n were plotted according to the type of procedure (Figures 1 and 2). The distributions shown in these figures are skewed distributions characterised by a main peak, a tail and some extreme values, which is typical of fluoroscopy-guided procedures. The mean values of DAP, T and n were determined for all the centres that provided data for more than 15 cases for each procedure and are illustrated in Figure 3 for the cardiology procedures and Figure 4 for the procedures on the lower limbs. Non-academic and academic centres are depicted in dark grey and light grey, respectively. The horizontal line in the graphs illustrates the corresponding national RLs. For DAP of CA procedures (Figure 3a), three non-academic centres exceeded the RL by 90, 10 and 140 %, while one academic centre was found over the RL by 30 %. For these four centres, the T was also found to exceed the RL. However, only for centre 19 was the n found over the corresponding RL, while for centres 4 and 27, the n was found to be particularly low. For PCI procedures, only five centres provided a sufficient number of cases for further analysis, two of them being academic. One non-academic and one academic centre exceeded by 60 and 82 %, respectively, the national RL for the DAP. However, the T and n for these two centres were found below the RLs. The centre 19 was found to exceed the RLs for both CA and PCI procedures. In Figure 4a, the DAP for centres 10 and 105 exceeded the RL for AngioLL procedures. For all centres, T and n (with the exception of centre 105, Figure 4c) were found to be within the national RL (Figure 4b–c). In case of PTALL procedures, the DAP was found well below the RL for all non-academic centres and only the academic centre 103 was found to be over the RL. On the contrary, T was found to exceed the RL for almost all centres, while in Figure 4f, for n the RL was exceeded by two non-academic centres. A closer investigation was performed for the non-academic centres, where the mean DAP value was found to exceed the RLs while the mean T and n values were found below the corresponding RLs. The ratios between the DAP value of the X-ray unit and the reference DAP for the centre 19 (Figure 3d) and 10 (Figure 4a) were 1.2 and 1.1, respectively. The same investigation was performed for the centres 10, 20, 28 and 30 (Figure 4d), where the T and n values were found to exceed the RLs, but DAP values were below the corresponding RL. The ratio for the centres 10, 20, 28 and 30 were 1.1, 1.2, 1.3 and 1.1, respectively.

Academic and non-academic centres were compared in terms of DAP, T and n. The detailed analysis for the academic centres is not presented as it was not within the scope of this article. Table 3 includes the mean values, the 25th, 50th and 75th pctile for academic and non-academic centres, as well as U and p-values of M–W tests. The results showed no statistically significant difference for cardiology procedures in terms of DAP and T. On the contrary, differences occurred in n obtained during the procedures. Significantly more images were obtained in non-academic centres than in academic ones. In the case of AngioLL and PTALL procedures, significantly lower DAP values (51 and 64 Gy cm^2) were found when performed in non-academic centres than the corresponding DAP values

Table 2. Mean value, range and 75th pctile for DAP (Gy cm^2), T (min) and n for four procedures performed in non-academic centres.

Procedure	CA	PCI	AngioLL	PTALL
Number of cases	311	119	101	243
DAP (Gy cm^2)				
Mean	87	91	51	64
Range	3–1277	4–434	7–765	36–1017
75th pctile	102	125	42	67
T (min)				
Mean	32	14	6	18
Range	1–40	1–42	1–28	1–151
75th pctile	10	19	8	23
n				
Mean	1039	1277	129	164
Range	8–4382	12–3196	6–390	5–1518
75th pctile	1549	1837	154	196

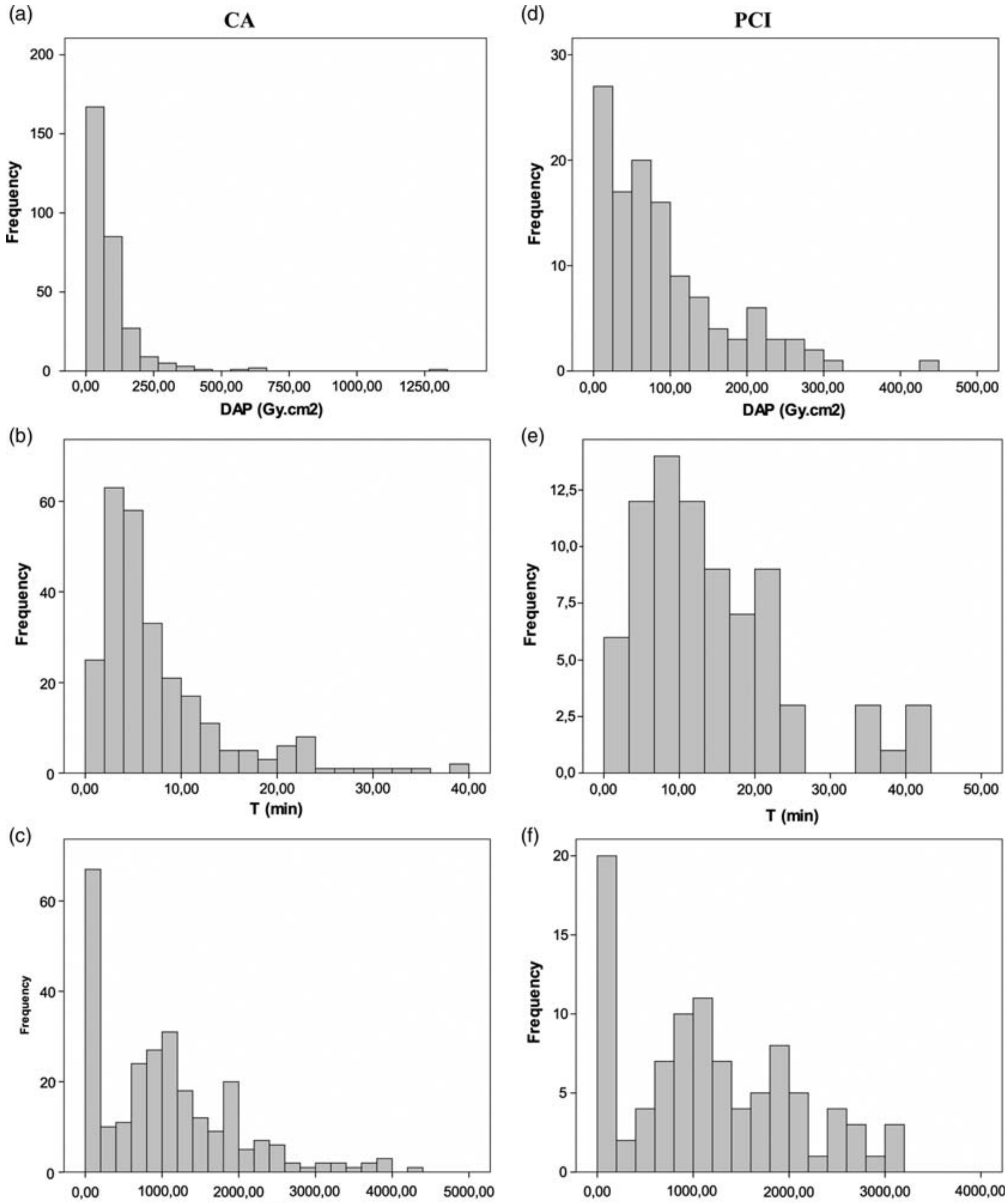

Figure 1. Overall distribution of the DAP (Gy cm^2), *T* (min) and *n* for non-academic centres for CA and PCI procedures.

(172 and 334 Gy cm^2) for academic ones. *T* was found lower for AngioLL procedures in non-academic centres. However, for PTALL procedures, performed in non-academic centres the *n* obtained during the procedure was found to be significantly higher than the one obtained in academic centres.

DISCUSSION

Four commonly performed procedures in interventional cardiology and radiology were investigated in non-academic centres by plotting the distributions of DAP, *T* and *n*. For a number of centres the mean

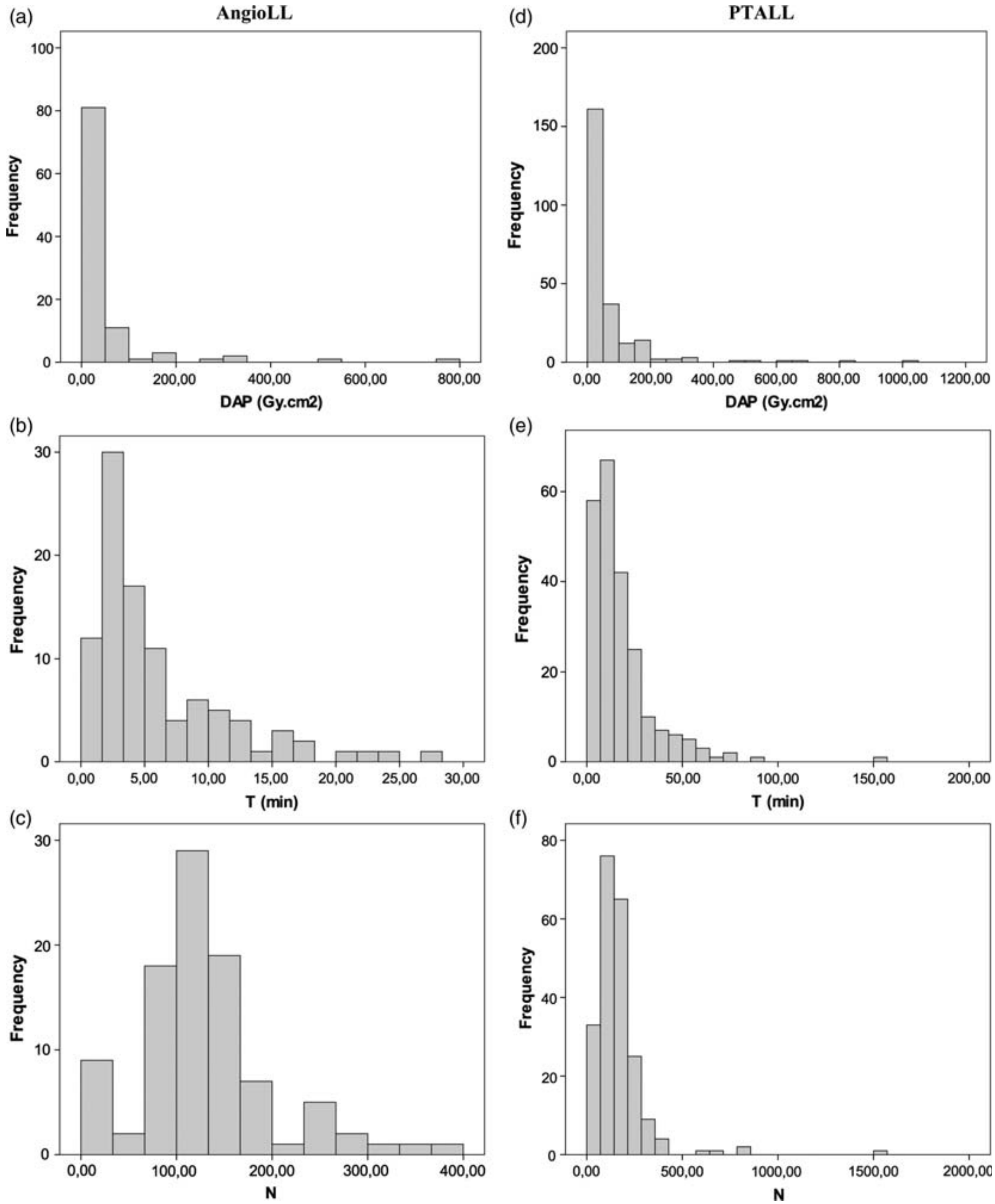

Figure 2. Overall distribution of the DAP (Gy cm^2), T (min) and n for non-academic centres for AngioLL and PTALL procedures.

values of DAP, T and n were estimated and compared with national RLs, revealing that national RLs were only occasionally exceeded. Non-academic centres were compared in terms of DAP, T and n with previously collected data from academic centres from 1 y ago. For cardiology procedures, no significant differences in the patient dose were found between non-academic and academic centres. The results here, however, showed that the patient dose for interventional radiology procedures performed in

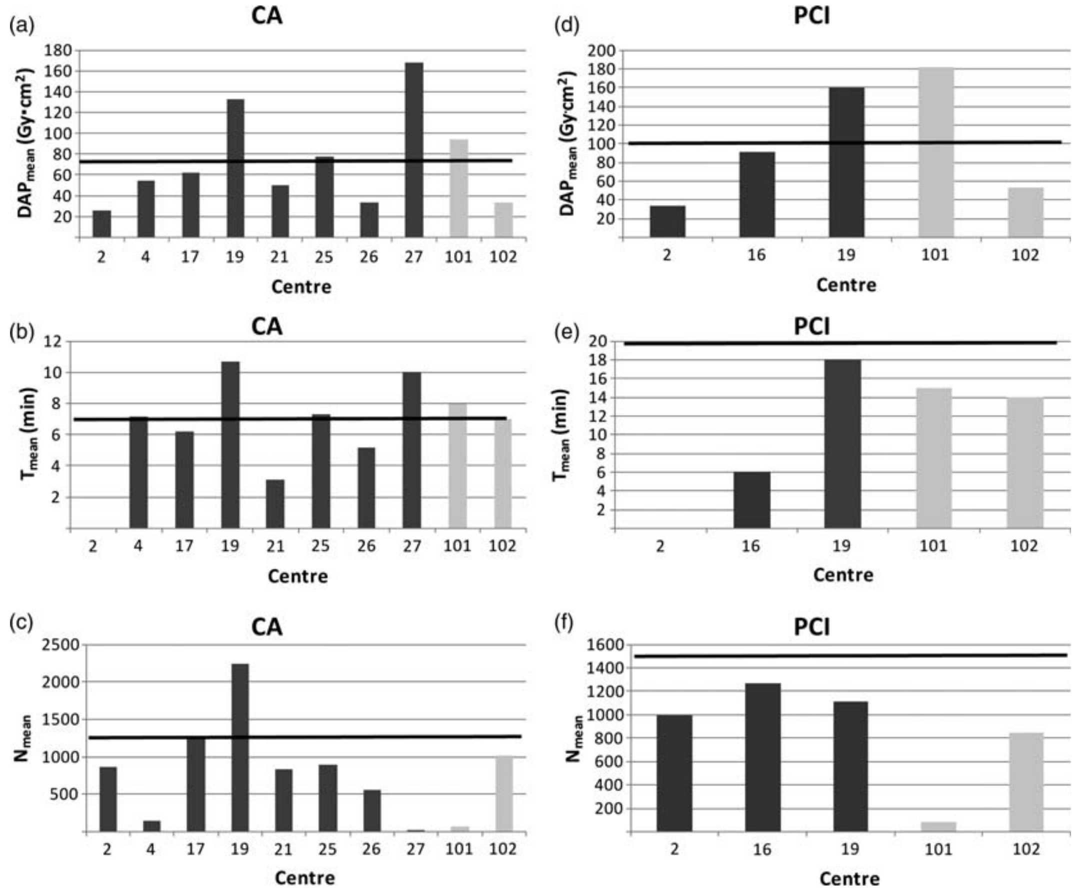

Figure 3. Mean values of the DAP (Gy cm^2), T (min) and n for non-academic (in dark grey) and academic centres (light grey) for CA and PCI procedures and comparison with the national RLs (horizontal black line).

non-academic centres was lower and did significantly differ from that performed in academic ones (Table 3). As there were no significant differences between patient demographics in the two types of centre, this may indicate a difference in the experience of operators or the complexity of the procedures.

Although radiation exposure is affected by factors such as T and n, there were cases, for instance centre 19, in Figure 3d–f, where the mean value for DAP surpassed the corresponding RL value, with T and n values being well below the RLs. On the other hand, there were cases where the DAP values were lower than the RL, while T and n values exceeded the corresponding RLs (centres 10 and 30, Figure 4d–f). This may be attributed to large X-ray fields or the use of high dose settings. This is also supported by the fact that the ratios between the installation DAP meter and the reference one are comparable between centres where DAP values exceeded the national RLs and centres where the T and n values exceeded the RLs, but the DAP was found well below the corresponding one. Although, Swiss legislation demands the use of DAP, T and n for comparison with the RLs, there were centres that failed to provide data for all three parameters. Reports prepared by the Federal Office of Public Health with specific results and recommendations on how to optimise patient exposure were sent to each centre that participated in the study. The establishment and use of local RLs were encouraged, especially for the cases of AngioLL and PTALL procedures performed in non-academic centres.

The use of well-defined RLs allows physicians to further optimise their technique. Bearing in mind that advances in technology and operator experience have allowed more challenging patient subsets to be treated by percutaneous interventional procedures, RLs should be regularly updated taking into account changes in everyday clinical practice. The results here

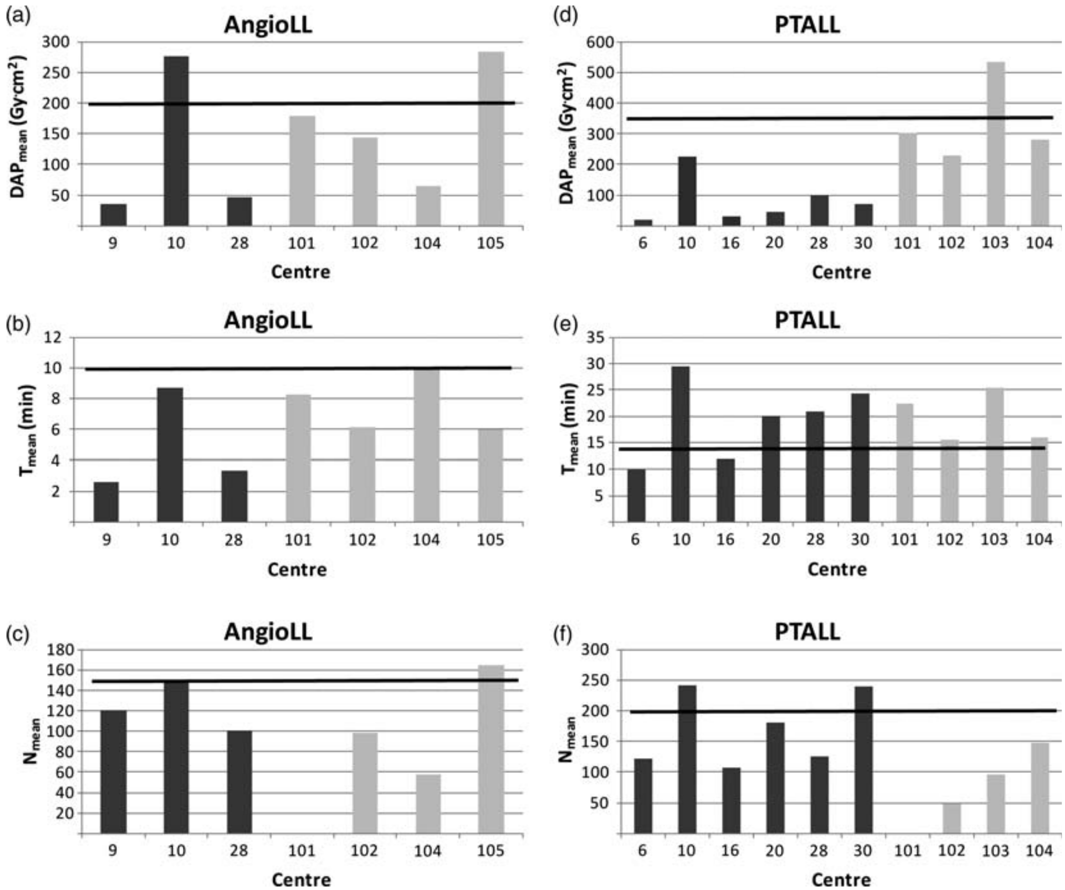

Figure 4. Mean values of the DAP (Gy cm^2), T (min) and n for non-academic (in dark grey) and academic centres (light grey) for AngioLL and PTALL procedures and comparison with the national RLs (horizontal black line).

revealed that for cardiology procedures, no major differences in the patient dose existed between the two types of centres, while for AngioLL and PTALL procedures significantly higher doses were found in academic centres. How should the RLs be more accurately defined? Taking into account differences in the workload of the centre, as defined by ACC/AHA guidelines[10], for example, one may overlook the fact that in academic centres with high workloads, trainees perform many simple procedures, while more experienced operators perform complex procedures. Thus, high patient doses may be attributed either to the inexperience of the operator or to the difficulty of the procedure. Furthermore, taking into account the experience of the operator[10], fact that more than one operator may perform the procedure is neglected. However, this approach could be followed partially as these kinds of guidelines exist only for interventional cardiology. Should the complexity of the procedure be taken into account when defining the RLs values? Complexity is affected by factors related to the patient (for instance, patient size, patient anatomy and severity of the pathology). High patient doses are not necessarily linked to complex procedures and in these cases, dose optimisation is required. Indeed, in this work, no significant differences in patient collection were revealed between non-academic and academic centres. Some authors have already proposed the use of complexity indices to characterise cardiac interventional procedures considering factors such as the number of vessels treated and the number of stents placed during the procedure[11–13]. Complexity indices may have a role as an objective method to define the nature of the procedure. No such index exists currently for interventional radiology.

RLs are dynamic and change according to the distribution of doses encountered in contemporary practice. Their establishment is the first step for optimisation. The second step is to regularly control and, if necessary, to update the RL values. The

Table 3. Mean values, 25th, 50th, 75th pctile and M–W test results for DAP, *T* and *n* for the four procedures performed in non-academic (NA) and academic (A) centres.

Type of procedure	Type of hospital (number of cases)	DAP (Gy cm^2)	*T* (min)	*n*
CA	NA (311)			
	Mean	87	32	1039
	25th pctile	32	3	180
	50th pctile	58	5	935
	75th pctile	102	10	1549
	A (49)			
	Mean	65	7	510
	25th pctile	22	3	45
	50th pctile	45	5	84
	75th pctile	90	9	1150
	U, *p*-value	NS	NS	4218, $p < 0.001$
PCI	NA (119)			
	Mean	91	14	1277
	25th pctile	27	7	514
	50th pctile	67	12	1029
	75th pctile	125	19	1838
	A (33)			
	Mean	104	14	545
	25th pctile	30	8	29
	50th pctile	90	15	119
	75th pctile	170	21	826
	U, *p*-value	NS	NS	811.5, $p = 0.012$
AngioLL	NA (101)			
	Mean	51	6	129
	25th pctile	11	2	93
	50th pctile	20	4	120
	75th pctile	42	8	154
	A (74)			
	Mean	172	7	110
	25th pctile	58	4	17
	50th pctile	148	5	116
	75th pctile	226	9	177
	U, *p*-value	1244, $p < 0.001$	2895, $p = 0.018$	NS
PTALL	NA (243)			
	Mean	64	18	164
	25th pctile	9	7	87
	50th pctile	23	13	142
	75th pctile	67	23	196
	A (72)			
	Mean	334	19	97
	25th pctile	151	10	15
	50th pctile	262	16	71
	75th pctile	426	27	156
	U, *p*-value	1238, $p < 0.001$	NS	4347, $p < 0.001$

NS, non-significant.

application of the RLs is resource intensive. Thus, the role of a medical physicist in an interventional department may need to be re-examined. Advances in medical equipment, such as catheters and stents, have allowed physicians to perform more complex procedures, leading to high radiation exposure of both patient and personnel. Modern X-ray units with FP detectors and a wide choice of dose settings may reduce X-ray exposure. A close collaboration between medical physicists and physicians helps the former understand the imaging needs and properly set the X-ray unit and the latter ensure the correct use of modern equipment. Optimisation of patient exposure can only be performed when physicians' need for imaging is taken into account. Clinical medical physicists are needed to exploit the sophisticated medical techniques that are becoming more and more available in the field of interventional radiology.

The use of FP detectors instead of II in this study was shown to have no influence on patient doses during cardiology procedures. Although FP detectors may provide good quality images using lower doses than II, their use proved to lead to either equivalent dose levels[14] or even to a dose increase[15–17]. Only in one publication was it reported that the patient dose decreased when using FP detectors, and this was mainly due to the continuing education of the cardiologists[18]. To reduce patient exposure, the use of FP detectors has to be accompanied by actions, such as using the low-dose mode and additional beam filters.

This study has its limitations. Some of the addressed non-academic centres did not complete the study or sent less data than required. This may be attributed to the fact that the process of collecting data is both time and energy consuming. As the number of interventional procedures performed under fluoroscopy guidance is rising and the legal framework requires the monitoring of patient doses, there is an urgent need to use automated methods of data collection. Certain departments, most of them cardiology departments, have already installed an automatic database, hence reducing the collection time and making data more accurate.

CONCLUSION

This study aimed to evaluate the patient radiation dose for four common fluoroscopy-guided procedures performed in non-academic centres. The results here revealed that the patient radiation dose in non-academic centres may differ from that in academic ones. For cardiology procedures, radiation doses were comparable in academic and non-academic centres, whereas radiation doses were found to be significantly lower for procedures of the lower limbs performed in non-academic centres when compared with academic centres. A number of centres were found to exceed national RLs, especially for cardiology procedures. However, for procedures of the lower limbs, doses were found to be well below the RLs. Written instructions to the non-academic centres were sent suggesting optimisation of patient exposure by controlling the X-ray field, reducing fluoroscopy time and number of images obtained during the procedure. National RLs may need to be updated taking into account differences among centres.

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