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Original paper

Establishing the European diagnostic reference levels for interventional cardiology

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ABSTRACT

Interventional cardiac procedures may be associated with high patient doses and therefore require special attention to protect the patients from radiation injuries such as skin erythema, cardiovascular tissue reactions or radiation-induced cancer. In this study, patient exposure data is collected from 13 countries (37 clinics and nearly 50 interventional rooms) and for 10 different procedures. Dose data was collected from a total of 14,922 interventional cardiology procedures. Based on these data European diagnostic reference levels (DRL) for air kerma-area product are suggested for coronary angiography (CA, DRL = 35 Gy cm^2), percutaneous coronary intervention (PCI, 85 Gy cm^2), transcatheter aortic valve implantation (TAVI, 130 Gy cm^2), electrophysiological procedures (12 Gy cm^2) and pacemaker implantations. Pacemaker implantations were further divided into single-chamber (2.5 Gy cm^2) and dual chamber (3.5 Gy cm^2) procedures and implantations of cardiac resynchronization therapy pacemaker (18 Gy cm^2). Results show that relatively new techniques such as TAVI and treatment of chronic total occlusion (CTO) often produce relatively high doses, and thus emphasises the need for use of an optimization tool such as DRL to assist in reducing patient exposure. The generic DRL presented here facilitate comparison of patient exposure in interventional cardiology.

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1. Introduction

Interventional cardiac procedures can produce high patient doses and therefore require special attention to protect the patient from radiation injuries such as skin burns, cardiovascular tissue reactions or radiation-induced cancer [1]. In the early days of interventional radiology and cardiology the procedures and techniques were straightforward and the required fluoroscopy time was short. The introduction of more sophisticated catheters and stents in 1980's and 1990's led to more complex and time-consuming operations, thus increasing both patient and operator exposures [2]. Even though the use of fluoroscopy in medical procedures has a long and successful history, reported severe radiation-related injuries such as skin burns were relatively rare until 1990's. With technological advances, new techniques and procedures with potentially high-doses have been introduced recently, such as transcatheter aortic valve implantation (TAVI) and treatment of chronic total occlusions (CTO). At the same time, the technological advances such as reduced frame rates, virtual collimation, noise suppression etc. may compensate the potential increase in patient exposure.

One essential tool to promote optimization in interventional procedures is the diagnostic reference level (DRL). The use of DRLs is emphasized also in the new European Basic Safety Standard [3]. However, since the implementation of DRLs in interventional procedures varies significantly with the complexity and are only applicable to groups of patients, alert levels have been introduced to indicate doses that are high enough to cause tissue reactions such as skin effects on individual patients [4,5]. Alert levels typically use the online dose indicator (e.g. air kerma-area product P_{KA} or cumulative air kerma at patient entrance reference point C_K [6]) to estimate the peak skin dose to the patient.

Ideally, the DRLs should be set and regularly updated at a national or even at local (hospital) level. Then, each hospital performing the respective procedures should audit their patient doses to calculate their median values to ensure that they do not exceed the corresponding reference levels. However, some high-dose procedures are relatively new or done infrequently, hence setting local, national or regional DRLs is not always appropriate at the onset of operation. To provide basis for optimization, European DRLs in interventional cardiology (IC) have been suggested ten years ago in the SENTINEL project for some of the most common cardiac procedures [7]. Recently, in the European Union there have been several DRL studies in coronary angiography (CA) and percutaneous coronary intervention (PCI) [8–16], and also a few studies on pacemaker implantations (PI) and electrophysiological procedures (EF) [8,10,14,16]. However, for TAVI, pacemaker implantation and electrophysiological procedures the published DRLs remain scarce. One of the most recent examples is the Finnish national set of DRLs in cardiology [16]. If several national DRLs exist for a specific procedure, the simplest way of establishing a regional (i.e. group of countries) DRL is to use the national DRLs [17]. However, in the case of IC, the DRLs exist mostly for CA and PCI procedures and a separate survey is needed for other procedures. ICRP [17] suggests that the DRLs should be revised at regular intervals not exceeding 5 years.

In this work a study covering selected centers from 13 countries and 10 different cardiac procedures was conducted. The main goal of this study was to propose new European DRLs for selected common or recently introduced IC procedures. In addition to patient exposure parameters, some parameters related to patient physiology and execution of the procedure were also collected and were used to study the dependence of patient dose indicators on these parameters. The results of this study can be used to promote optimization in patient protection before national or local DRLs are set and also to provide a basis for comparison when these levels are being set.

2. Materials and methods

The data was collected from 12 European countries (Belgium (BE), Croatia (HR), Czech Republic (CZ), Finland (FI), France (FR), Greece (GR), Ireland (IE), Poland (PL), Serbia (RS), Spain (ES), Sweden (SE) and Switzerland (CH)) and Lebanon (LB). This included 37 clinics and nearly 50 interventional rooms. The IC procedures taken into consideration were coronary angiography (CA), percutaneous coronary intervention (PCI), pacemaker implantation (PI), electrophysiological procedures (EF) and transcatheter aortic valve implantations (TAVI). The chronic total occlusions (CTO) were considered separately for PCI, when the separation was reported by the hospital. Pacemaker implantations were further divided into single (SCH) and dual chamber (DCH) procedures and implantations of cardiac resynchronization therapy (CRT) pacemaker. Electrophysiological procedures were divided into atrioventricular nodal reentrant tachycardia (AVNRT), atrial flutter (FL) and atrial fibrillations (AF). The majority of the data was collected between years 2015 and 2017 using Excel data collection sheets, the rest being collected between 2011 and 2014 from hospital information systems. In total, data for 14,922 procedures were collected. The data were corrected for obvious errors (e.g. incorrect P_{KA} units) and then verified by medical physics experts from each participating hospital or institution.

The procedures and corresponding patient distributions are summarized in Table 1. Other collected parameters were

- Date of procedure
- Access route
- Classification of PCI procedures (elective PCI or CA followed by an ad hoc PCI)
- Number of images
- Fluoroscopy time (FT)
- Total exposure time (including both FT and cine time)
- Fluoroscopy air kerma area product (P_{KA})
- Total P_{KA}
- Cumulative air kerma at patient entrance reference point (C_K) [6]

The data were analyzed with R code, version 3.3.2 [18]. The DRLs were determined as a 75% level (third quartile) of the distribution of quantity under review (e.g. P_{KA} or C_K). To get European values, the median of the quantity under review for each country was calculated. The DRL was then calculated as the third quartile of these median values. Pearson and Spearman correlations were used to examine the

Table 1
Procedures for which the data were collected, number of procedures and characteristics of patient distributions. Data for PI was evenly distributed between SCH, DCH and CRT procedures.

Procedure	n	Mean age (y)	Sex	Mean mass (kg)	Mean height (cm)
CA	4319	67	F: 35%, M: 65%	81	171
PCI	6467	66	F: 25%, M: 75%	82	171
CTO	192	64	F: 13%, M: 87%	82	172
PI	1587	72	F: 33%, M: 67%	81	171
EF	1462	57	F: 36%, M: 64%	84	173
TAVI	895	82	F: 51%, M: 49%	74	164

dependence of patient dose on exposure and physiological parameters.

Medical physics experts of participating hospitals were responsible for the quality assurance of the X-ray equipment in question. The acceptability criteria for the P_{KA} meter (or C_K) accuracy and calibration practices of these meters vary from country to country. However, as multiple X-ray devices and centers participated in the study, it is expected that this random variation does not introduce significant systematic change to the median (or third quartile) values. The expected maximum standard deviation in P_{KA} values can be estimated from the suggested European acceptability criteria [19] and from P_{KA} uncertainty data obtained from some participating clinics. Here, it is assumed that the errors follow a uniform distribution from −25% to +25% (which is slightly lower than the suggested European acceptability criteria of 35%), and thus the resulting standard deviation of P_{KA} values is 14% [5]. For example, in Sweden a more detailed analysis of P_{KA} meter uncertainty showed that the uncertainty range was −8% to +13%, i.e. compatible with the assumed standard deviation. In Croatia the standard uncertainty in P_{KA} was 6%, in Greece 23% and in Serbia and in Lebanon 10% (Serbian data was corrected to account for this). In Ireland the uncertainty ranged from 4% to 24% depending on the system. The attenuation caused by patient table and mattress was usually not accounted for to set the DRLs. However, this attenuation should be considered when P_{KA} is used to estimate the organ and effective doses of the patient.

The outliers in the data were examined by comparing the ratio of P_{KA} and C_K to the average value of this ratio which was calculated separately for each country and each procedure where high outliers are present and when hospitals reported the C_K values.

3. Results

The median total P_{KA} values for each procedure and each country are given in Table 2. The distributions of total P_{KA} values for CA, PCI, TAVI, PI and EF procedures are shown in Fig. 1. The corresponding values for cumulative air kerma are given in Table 3. Not all centers could report the air kerma values, hence there are fewer entries in Table 3 than in Table 2. In the last column the third quartile of these median values is calculated. The suggested European DRLs based on these 3rd quartiles are given in Table 4. The DRLs for CTO and for each separate EF procedure are not given in Table 4 since only few countries reported P_{KA} or air kerma data for these procedures. However, the 3rd quartiles are reported in Tables 2 and 3 for comparison.

The median P_{KA} values and resulting 3rd quartiles were also calculated with the patient weights restricted to 70–90 kg interval (see Table 1). Generally, the 3rd quartile values increased slightly, but in PCI the value decreased by 20%. Georges et al. [15] came to a conclusion that DRLs can be reliably estimated from the data including all the patients, regardless of the weight. The suggested DRL values in Table 4 are based on data including all the patients.

The patient exposure in cardiac procedures is affected more by procedure complexity than patient mass [17]. However, ICRP [17] suggests that the data are compensated for the differences in patient mass and body habitus. The results of this study show that the correlations between the patient mass and the total P_{KA} of the procedure are present. Based on the Pearson and Spearman correlation analysis, a significant correlation ($p < 0.05$) exists between patient mass and total P_{KA} for CA, PCI and TAVI procedures for most countries. The Spearman rank correlation coefficients were in the range 0.39–0.62 (CA), 0.31–0.75 (PCI) and 0.26–0.89 (TAVI) for countries with $p < 0.05$. For other procedures the correlations are either weaker or the amount of data is insufficient to draw definitive conclusions and further stratification may be needed to reveal the possible correlation. However, the thickness of the patient at the chest level and mass may not strongly be correlated. Therefore body mass index (BMI) was also used in correlation analysis. However, the use of BMI instead of patient mass did not improve the correlation coefficients. All countries did not report the patient height and therefore BMI could not be extensively calculated.

PCI procedures were classified into three categories, namely elective PCI, CA followed by an ad hoc PCI and CTO procedures. Elective PCI and ad hoc PCI categories had approximately the same number of procedures. However, the median P_{KA} value associated with ad hoc PCI procedures (62 Gy cm^2) was significantly higher than that of elective procedures (36 Gy cm^2). The median P_{KA} for pooled PCI (excluding CTO) procedures was 60 Gy cm^2. The P_{KA} in CTO was significantly higher than in other PCI procedures.

For TAVI procedures transfemoral access resulted in higher median P_{KA} than transapical access, 108 Gy cm^2 vs. 69 Gy cm^2, respectively. Only one transaortic access was reported, with relatively high P_{KA} 360 Gy cm^2. Transfemoral access was the most common, although only 31% of TAVI procedures included information on access route. TAVI patients are, on average, older and lighter than other patients (Table 1).

Some outliers (high P_{KA} values) are present in data, see Fig. 1. High P_{KA} values could be a result from the use of a larger X-ray field size than normal. To examine this, the average ratio of P_{KA} and C_K was calculated separately for each country and each procedure where high outliers are present, and when hospitals reported the C_K values. This average value was compared to the P_{KA}/C_K ratio of outliers. In PCI and TAVI procedures there were no differences in ratios between the average and outliers. In CTO procedures there were no differences in Swedish data, but in French data the outliers are associated with approximately 1.5 times higher P_{KA}/C_K ratio.

The P_{KA} values increase with increasing fluoroscopy times, as expected. The 3rd quartile fluoroscopy times are 4 min (CA), 13 min (PCI) and 20 min (TAVI), calculated similarly to the DRL values in Tables 2 and 3. For CTO the 3rd quartile time is 53 min. For combined EF, the time is 9 min without Lebanese ablation data. In pacemaker implantation the 3rd quartile fluoroscopy times are 3.5 min (SCH), 5 min (DCH) and 12 min (CRT). However, FT is a poor indicator of a patient dose

Table 2
The median total P_{KA} values (in Gy cm^2) for each procedure and each country. The last two columns are the 3rd quartiles (without and with weight restriction) of the data on each row. The median P_{KA} values that are based on less than five data points are given in parentheses. DRL was calculated from medians with at least five data points. *Includes ablation. The 3rd quartiles in parenthesis are calculated without this values.

Procedure	BE	HR	CZ	FI	FR	GR	IR	LB	PL	RS	ES	SE	CH	3rd quartile	3rd quartile (restr)
CA	35.6		35.5	21.2	22.0	–	35.3	12.8	14.1	42.2	34.2	17.5	65.7	35.5	36.8
PCI	87.3	35.9	89.8	45.7	57.6	44.5	73.0	37.7	28.5	98.1	63.4	31.7	135	87.3	68
CTO	–	–	–	–	120	–	(271)	–	–	–	–	143	–	137	–
TAVI	(305.4)	(55.4)	130	89.4	134	193	87.1	99.2	–	–	25.9	87.2	96.8	130	140
PI SCH	–	–	2.18	1.86	–	5.60	2.63	2.40	–	2.97	–	1.43	–	2.80	3.8
PI DCH	–	–	2.28	3.20	–	(25)	2.53	3.84	–	5.16	–	0.86	–	3.65	4.23
PI CRT	–	–	18.4	31.4	14	6.63	15.8	4.96	–	19.2	5.82	4.13	–	18.4	20.8
EF AVNRT	–	–	0.97	3.67	–	–	(2.26)	–	–	–	–	2.73	–	3.2	4.75
EF FL	–	–	0.96	14.5	–	–	–	–	–	–	–	6.58	–	10.5	–
EF AF	–	–	2.51	29.2	–	–	4.84	–	–	–	–	8.41	–	13.6	16.0
EF ALL	–	–	1.09	14.5	3.5	5.28	3.5	109.1*	–	–	13.7	6.53	–	14.1 (11.9)	(13.5)

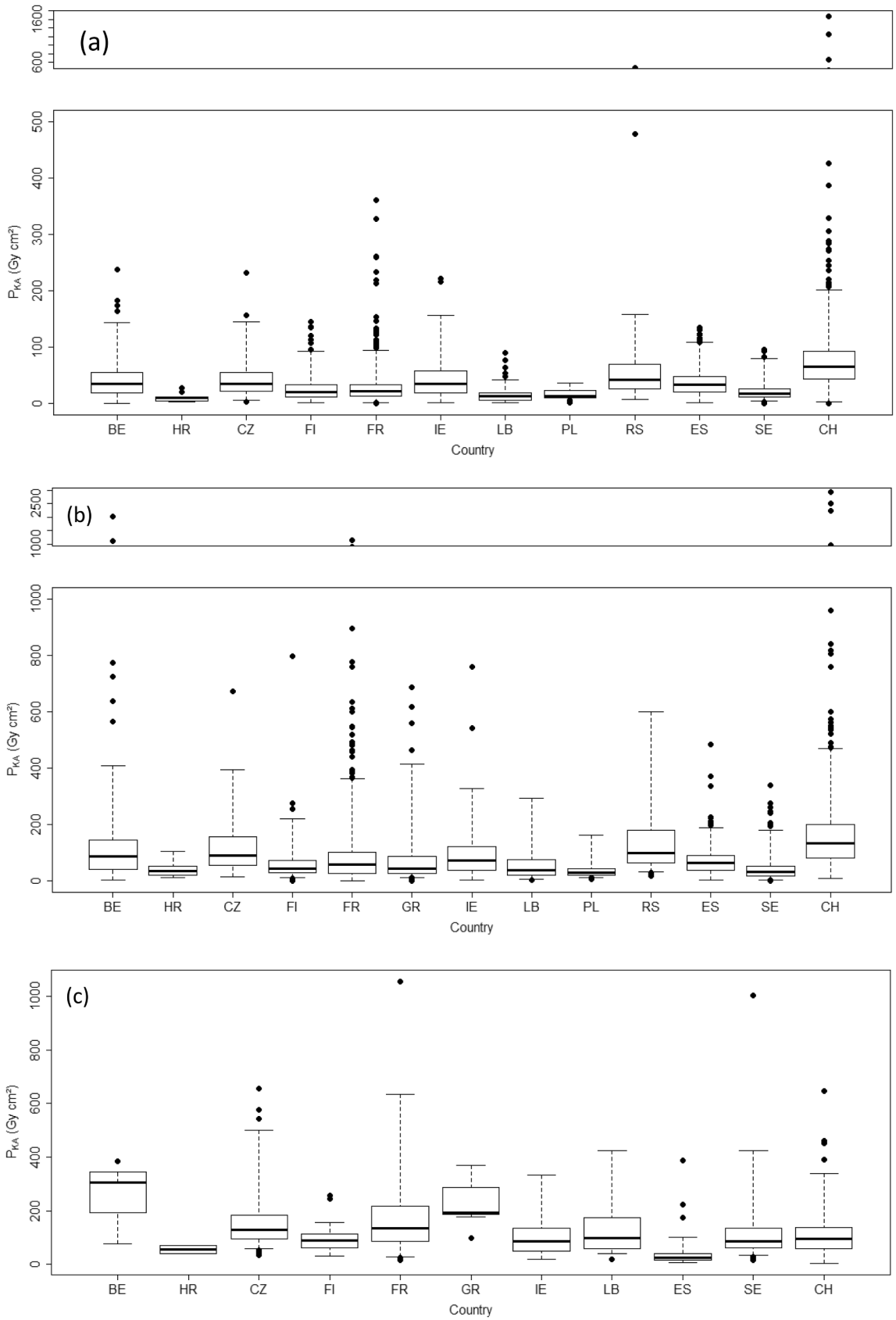

Fig. 1. Distribution of total P_{KA} values for each country. The data are for CA (a), PCI (b), TAVI (c), PI (d) and EF (e) procedures. The box represents the first and third quartiles and the line in between the median. The whiskers are drawn as adjusted boxplots [18]. The data points beyond these limits are drawn separately.

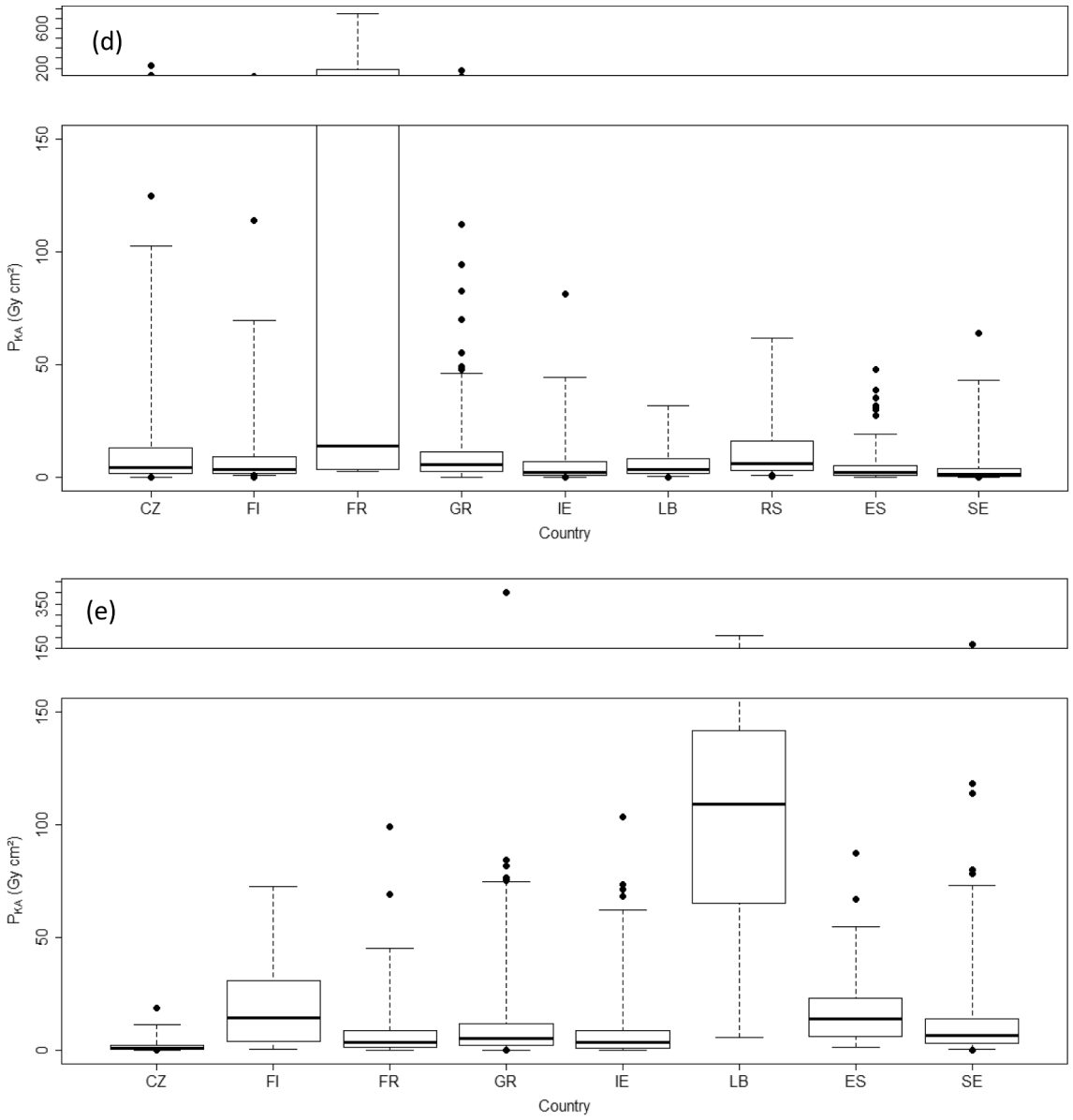

Fig. 1. (*continued*)

Table 3
The median cumulative air kerma C_K values (in mGy) for each procedure and each country. The last column is the 3rd quartile of the data on each row. The median C_K values that are based on less than five data points are given in parentheses. DRL was calculated from medians with at least five data points. *Includes ablation. The 3rd quartile in parenthesis is calculated without this value.

Procedure	BE	HR	CZ	FI	FR	GR	IR	LB	PL	RS	ES	SE	CH	3rd quartile
CA	478	178	359	299	274	–	416	186	271	486	578	–	–	463
PCI	1170	747	965	736	803	661	1631	602	626	1481	1320	–	–	1245
CTO	–	–	–	–	1467	–	(4352)	–	–	–	–	2204	–	2020
TAVI	(2123)	(537)	826	1292	894	1550	866	932	–	–	269	1196	810	1196
PI SCH	–	–	–	19	–	53	35	20	–	28	–	10	–	33
PI DCH	–	–	–	28	–	(238)	26	30	–	48	–	6	–	30
PI CRT	–	–	–	295	99	63	150	43	–	176	–	34	–	163
EF AVNRT	–	–	–	36	–	–	(23)	–	–	–	–	–	–	36
EF FL	–	–	–	150	–	–	–	–	–	–	–	–	–	150
EF AF	–	–	–	374	–	–	70	–	–	–	–	–	–	298
EF ALL	–	–	–	150	–	47	42	894*	–	–	–	–	–	150 (73)

Table 4
Suggested DRL (P_{KA} and C_K) for selected procedures. For electrophysiological procedures the DRL is given for the pooled AVNRT, FL and AF data. *Without ablation.

Procedure	CA	PCI	TAVI	PI SCH	PI DCH	PI CRT	EF ALL
Suggested DRL (P_{KA}, Gy cm^2)	35	85	130	2.5	3.5	18	12*
Suggested DRL (C_K, mGy)	460	1200	1200	30	30	160	70*

[17] and its use as a DRL quantity is not encouraged.

4. Discussion

The CA procedures that are followed by an ad hoc PCI procedure cause higher exposure compared to elective PCI procedures. One possible explanation for the difference may be that ad hoc PCIs are usually preceded by CA, whilst elective procedures are performed on stenotic parts which are known beforehand (e.g. from a previous CA). Therefore elective procedures start with known localization of the stenotic (or treated) part. In practice the registration of PCI procedures varies and it is possible that the classification of these procedures is mixed to some extent.

The highest variations in doses were encountered in TAVI and electrophysiological procedures. TAVI is a relatively new procedure, and it is expected that there is a steep learning curve within the first few months of operation (see e.g. Simard et al. [20]). Therefore larger variations than in established procedures are expected. In electrophysiology, the relatively low values reported from the Czech Republic partly result from the use of an electromagnetic mapping system that reduces the need for X-ray guidance. The EF data from Lebanon include radiofrequency cardiac ablations, which explain the significantly higher P_{KA} values than for other countries. Therefore the suggested DRL for EF was calculated without the Lebanese data.

4.1. Uncertainties

The data for each country were obtained from one or a few clinic(s). Therefore the median values may not be representative for the country in question and a separate national data survey should be done to establish national DRLs. However, at the European level, data representing nearly 50 individual interventional rooms from 13 countries should sufficiently reflect regional differences so that conclusions about the median values for each procedure can be drawn.

The uncertainty in obtained DRL values was assessed with a jackknife resampling approach, i.e. omitting each data point (the country-specific median value) in turn and analyzing the change in obtained DRL. As expected, the DRLs that are calculated from relatively few data points are sensitive to values that deviate significantly from the mean. One such example is the EF AF procedure with four data points, where the inclusion of Finnish data almost doubles the DRL calculated without this data. Therefore the DRL should be set based on sufficiently large data set. ICRP suggests [17] a collection of 10–20 facilities (and at least 20 data points per facility) in setting local DRLs. In CA, PCI and TAVI procedures where the data is most extensive, the changes in DRL are small: The DRL for CA is within 35.4 and 35.6 Gy cm^2, for PCI the range is from 77 to 88 Gy cm^2 and for TAVI from 122 to 133 Gy cm^2. Also for PI procedures the DRL is relatively stable, the changes are less than 20% from the given 3rd quartile.

As discussed above, the P_{KA} readings are assumed to have 14% standard uncertainty. However, the P_{KA} meters are regularly calibrated and checked by the medical physics experts. Therefore, when setting local DRLs, each clinic can reduce this uncertainty by correcting the P_{KA} reading with the associated calibration coefficient.

Table 5
Summary of published DRL studies from the past ten years.

Country	Diagnostic reference level for P_{KA} (Gy cm^2)					
	CA	PCI	CA + PCI	PI	EF	TAVI
SENTINEL study [7]	45	85			35	
Sweden [22]	80					
UK [8]	29	50		11		
Belgium [9]	71.3	106				
Ireland [10]	42	84	107	21		
Croatia [11]	32	72				
Bulgaria [12]	40		140			
Switzerland [13]	102	125				
USA [23]	83	193	199			
Greece [14]	53	129		36		
France [15]	38	80				
Finland [16]	30		75	3.5*	25**	90

* Does not include CRT.
** AF only.

Both university hospitals and non-academic hospitals participated in the present study. University hospitals are training centers for specializing physicians. Therefore higher dose levels may be expected in academic than in non-academic centers, thus producing some dispersion in the median values. However, the Swiss study by Samara et al. [13] did not find any significant differences between academic and non-academic centers in cardiac procedures. A recent Irish study [21] showed that local DRLs at one university hospital were lower than national DRLs.

4.2. Comparison to earlier studies

Several national DRL studies in cardiology have been published during the past ten years. A summary of these studies is presented in Table 5. Large variations between studies are evident even in the well-established procedures such as CA and PCI. The third quartiles of CA and PCI P_{KA} values from Table 5 are 73 Gy cm^2 and 125 Gy cm^2, respectively. These are higher than the values suggested in the present work.

The DRL values set in the SENTINEL project [7] for kerma area product were 45, 85 and 35 Gy cm^2 for CA, PCI and electrophysiological procedures, respectively. These can be compared to suggested DRL values of the present study, 35, 85 and 12 Gy cm^2, respectively. However, the electrophysiological procedures considered by Padovani et al. [7] included radiofrequency cardiac ablations, potentially leading to higher doses than the procedures considered in this study. Thus, in ten years the patient exposure in CA has decreased by approximately 20%, but on a collective level this decrease is compensated by more frequent use of angioplasty and an ageing population requiring more cardiac procedures – in 2014, angioplasty is used in more than 80% of all revascularization procedures in Europe. Ten years earlier the proportion was approximately 70% [24]. In future, advances in image post-processing may be beneficial for the patient exposure (see e.g. Lauterbach and Hauptmann [25] for an example in TAVI procedures). In this study an example is the low Spanish median P_{KA} for TAVI procedures that results from dose reduction technology based on image post-processing.

Larger doses are delivered in PCI procedures when the PCI was done ad hoc following the CA, compared to elective PCI. Bernardi et al. [26] considered the complexity index (essentially the lesion classification according to American Heart Association (AHA) and American College of Cardiology (ACC) grading system) of the PCI procedures and concluded that patients' exposures were statistically significantly different as a function of complexity index. In TAVI, transfemoral procedures resulted in larger doses than with transapical access. In transfemoral implantation the positioning of the valve is often more complicated than in transapical access due to the retrograde approach and more

radiation is needed to ensure the correct positioning. CTO procedures resulted in higher doses than other PCI procedures. For further discussion on CTO, see Maccia et al. [27] and Syrseloudis et al. [28]. Kottou et al. [29] concluded that the procedure complexity and technical factors have a major impact on dose levels in paediatric IC.

Alert levels have been introduced to correlate the maximum skin dose of the patient with the online dose indicators such as P_{KA} reported by the x-ray equipment (see e.g. [30]). In PCI procedures P_{KA} values between 150 and 300 Gy cm^2 have been suggested to correspond to the maximum skin dose of 2 Gy (see e.g. Järvinen et al. [5], see also Stecker et al. [31]). In the present data, 16% of PCI procedures resulted in P_{KA} value exceeding 150 Gy cm^2, 3% exceeded 300 Gy cm^2 and 1% exceeded 500 Gy cm^2. Although the alert levels are not directly applicable from one procedure to another, it is interesting to notice that more than 30% of TAVI and CTO procedures exceeded the 150 Gy cm^2 threshold and approximately 2% of them produced P_{KA} more than 500 Gy cm^2. Therefore reliable real-time monitoring systems for peak skin dose are urgently needed.

5. Conclusions

Advances in application of fluoroscopically guided cardiac procedures require up-to-date information on patient exposure. Essential tools in optimization of patient exposure are the DRLs. In this work new European DRL values are provided for some well established and for some relatively new cardiac procedures. The DRLs suggested in the present work are lower (CA, EF) or at the same level (PCI) than those obtained in the earlier SENTINEL study [7]. New DRLs are suggested for CTO, TAVI and PI procedures.

As many new procedures have a steep learning curve within the first few months of operation, local reference levels are difficult to set at the onset. In these cases generic DRL values such as those given in the present work can be applied. When the procedures are well established, local DRLs should be set since variations between countries or even within the country can be large.

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