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INVITED PAPER

REFERENCE LEVELS AT EUROPEAN LEVEL FOR CARDIAC INTERVENTIONAL PROCEDURES

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In interventional cardiology, a wide variation in patient dose for the same type of procedure has been recognised by different studies. Variation is almost due to procedure complexity, equipment performance, procedure protocol and operator skill. The SENTINEL consortium has performed a survey in nine european centres collecting information on near 2000 procedures, and a new set of reference levels (RLs) for coronary angiography and angioplasty and diagnostic electrophysiology has been assessed for air kerma-area product: 45, 85 and 35 Gy cm^2, effective dose: 8, 15 and 6 mSv, cumulative dose at interventional reference point: 650 and 1500 mGy, fluoroscopy time: 6.5, 15.5 and 21 min and cine frames: 700 and 1000 images, respectively. Because equipment performance and set-up are the factors contributing to patient dose variability, entrance surface air kerma for fluoroscopy, 13 mGy min^{-1}, and image acquisition, 0.10 mGy per frame, have also been proposed in the set of RLs.

INTRODUCTION

Interventional cardiology is a medical specialty widely known to potentially deliver high radiation dose to patients, who may receive, in some complex cases, high organ doses and skin doses over the threshold for deterministic effects.

The radiation dose depends on a number of factors, including patient size, equipment, technique and type of examination. Large variation in patient dose, for the same type of X-ray examination, has been demonstrated in several studies[1–5]. These variations are almost due to different complexities of the procedures, equipment performance, procedure protocols and patient body size.

By investigating the patient dose, variations can be acknowledged, causes can be found and necessary adjustments can be implemented.

Reference levels (RLs) provide a framework to reduce this variability and assist in the optimisation process[6–8]. For this reason, monitoring patient exposure in prolonged interventional procedures and comparison with RLs are mandatory tasks in every quality assurance programme.

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MATERIALS AND METHODS

A European survey was conducted by the SENTINEL consortium to investigate doses in selected interventional cardiac procedures and to establish updated RLs.

Cardiac procedures were divided into three main groups:

(1) coronary angiography (CA);
(2) percutaneous transluminal coronary angioplasty (PTCA);
(3) electrophysiology procedures, including diagnostic electrophysiology, pacemaker implantation, defibrillator implantation (ICI) and radiofrequency cardiac ablation (RFCA).

The survey involved nine European partners and near 2000 procedures were examined (Table 1).

Information, such as fluoroscopy time (FT), number of frames, air kerma-area product (KAP) and, when available, the cumulative dose (CD) to

Table 1. Cardiac interventional procedures in the sample of patient dose survey.

Procedure	No. of patients
Coronary angiography	672
Percutaneus transluminal coronary angioplasty	662
Electrophysiology diagnostic procedure	112
Pacemaker implantation	51
Radiofrequency cardiac ablation	337

interventional reference point (IRP), were provided. The accuracy of dose values provided has been submitted to a dosimetry intercomparison by the Lodz (Poland) partner.

RESULTS AND DISCUSSION

Coronary angiography procedures

Examined dose or dose analogue data exhibit a large variability. In Figures 1 and 2, mean and median values of FT and KAP, respectively, are reported for CA procedures.

The examinations have been pooled, and the frequency distribution of FT, number of frames and KAP have been derived together with the associated RLs. RLs have been assessed as the rounded values of the 75th percentile of distributions.

Figures 3 and 4 report the histograms of FT and KAP values, respectively, for all CA procedures evaluated in this study.

PTCA procedures

In Figures 5 and 6, histograms of FT and KAP, respectively, for PTCA procedures are reported.

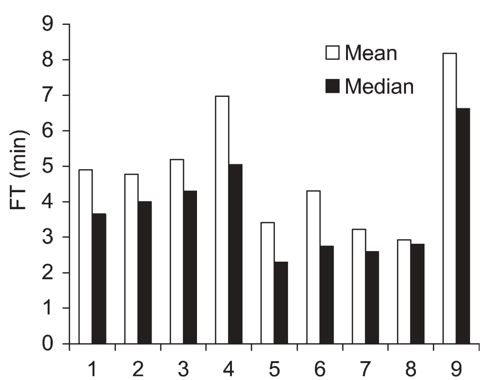

Figure 1. Fluoroscopy time of CA procedures in the nine participating centres.

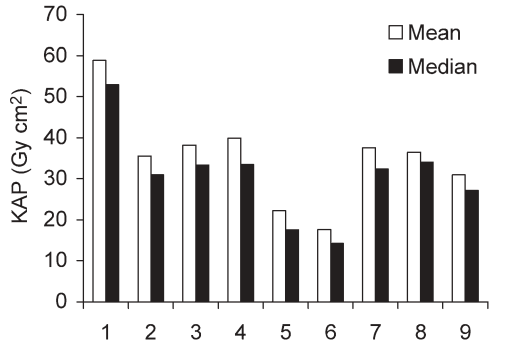

Figure 2. Air KAP of CA procedures in the participating centres.

Electrophysiology procedures

Frequency distribution histograms approximate a log-normal shape in all cases. This result represents the effects of differences between patient sizes and

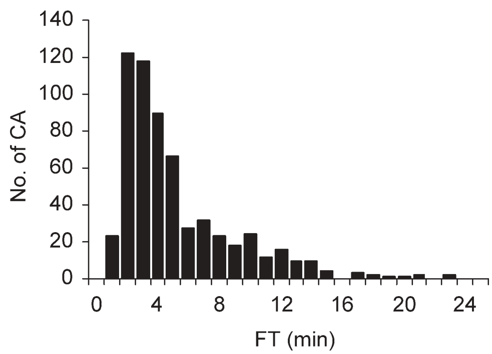

Figure 3. Frequency distribution of FT for CA procedures.

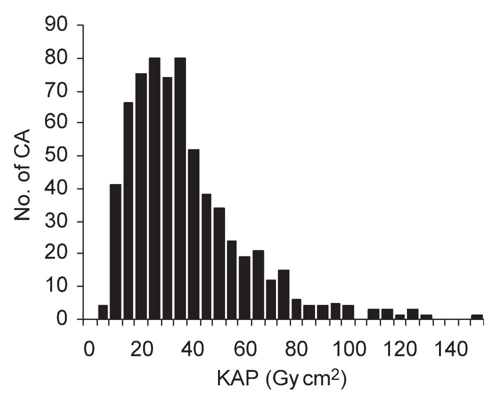

Figure 4. Frequency distribution of air KAP for CA procedures.

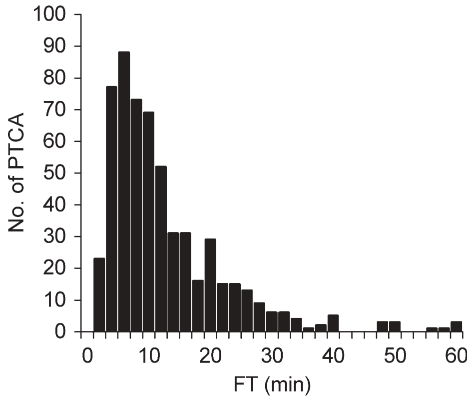

Figure 5. Frequency distribution of FT for PTCA procedures in participating cardiac centres.

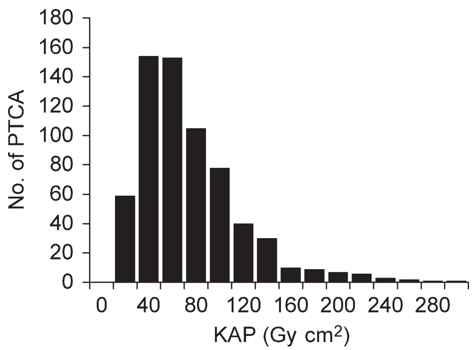

Figure 6. Frequency distribution of air KAP for PTCA procedures in participating cardiac centres.

procedure protocols, as well as technical differences between equipment.

Reasons arise from a variety of RFCAs performed to treat different arrhythmias: atrial fibrillation, atrial flutter, nodal tachycardia, ventricular tachycardia and Wolff-Parkinson-White syndrome (WPW). Important differences in procedure protocols provide different mean FT and KAP values.

In Figure 7, the frequency distribution of FT for RFCA procedures is reported and it is possible to recognise the distribution does not have a log-normal shape.

Figures 8 and 9 report the data from an electrophysiology laboratory (Udine Hospital, Italy), where the information on type of RFCA have been collected. It is possible to recognise that the treatment for atrial fibrillation is the procedure that requires the highest FT (median value of 45 min) and, consequently, the highest KAP (median value of 35 Gy cm^2) values.

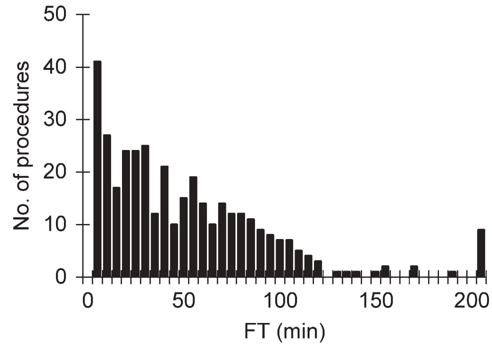

Figure 7. Frequency distribution of FT for electrophysiological procedures.

The data of electrophysiology collected in the Udine Hospital imply the impossibility to pool all RFCA data together.

In contrast, the data available for each single procedure are insufficient to treat them separately. Consequently, from this survey, it is not possible to assess RLs (DRLs) for RFCA procedures.

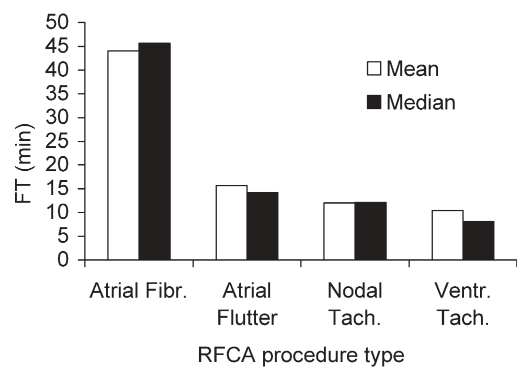

Figure 8. FT of different types of RFCA procedures.

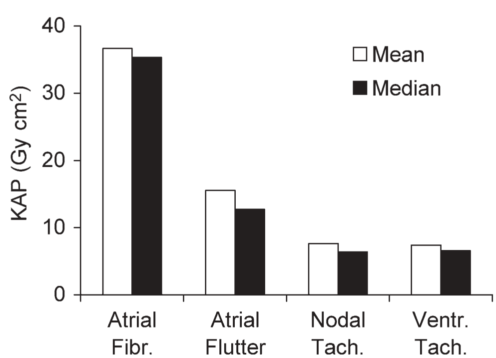

Figure 9. KAP of different types of RFCA procedures.

Table 2. SENTINEL RLs for interventional cardiac procedures.

Dose or dose analogue	Procedures		
	CA	PTCA	EFO
KAP (Gy cm^2)	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	—
FT (min)	6.5	15.5	21
Number of cine images	700	1000	—
Entrance surface air kerma rate	Fluoro low: 13 mGy min^{-1} Image acquisition: 0.10 mGy per frame		

Reference levels

In Table 2, RLs, assessed as the rounded value of the 75th percentile of distributions, are reported for FT, KAP, CD at IRP, effective dose (defined as $E = 0.18 \times$ KAP) and number of cine images.

Because equipment performance and set-up by the maintenance service are also important factors contributing to patient dose variability, entrance surface air kerma for fluoroscopy and image acquisition, measured at the entrance of a 20 cm PMMA phantom, are also introduced in the set of proposed RLs.

The RLs proposed for coronary angiography and angioplasty are lower when compared with those assessed in 2004 by the DIMOND group (CA:KAP = 57; PTCA:KAP = 94 Gy cm^2)[7]. The main difference derives from the lower number of cine images that had influenced the KAP.

Regarding the introduction of the CD at IRP in the set of RLs, it is necessary to better evaluate the impact of this quantity in the optimisation process of patient exposure.

CONCLUSION

The SENTINEL survey performed on interventional cardiology in a sample of European centres demonstrates the presence of a large variability in the entrance surface air kerma rates for both fluoroscopy and image acquisition modes. For the first time, RLs for these quantities are proposed to be used in the process of optimisation of patient exposure.

The SENTINEL RLs assessed also include the effective dose, calculated from the KAP reference value, and the CD at the IRP, quantity today displayed in the interventional room by the new equipment.

FUNDING

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