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Local diagnostic reference levels for cardiac implantable electronic device procedures: data from a tertiary care centre

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Summary

AIM: To establish local diagnostic reference levels for cardiac implantable electronic device procedures and to compare local practice with national guidelines.

METHODS: A retrospective cohort study including all consecutive patients from October 2018 to October 2020 who underwent implantation of a cardiac implantable electronic device including pacemaker, implantable cardioverter defibrillator (ICD), cardiac resynchronisation therapy (CRT) or lead extraction / device explantation. Data was collected from a dose management system and cross-checked for accuracy with the patient information system. The prespecified outcome was patient radiation exposure, evaluated with the kerma area product (KAP), cumulative dose, fluoroscopy time and number of cine acquisitions. The median values were set as local diagnostic reference levels.

RESULTS: A total of 541 patients were included. 28.3% had a conventional pacemaker, 22.0% a leadless pacemaker, 21.1% an ICD and 17.2% a CRT implanted, while lead extraction / device explantation was performed in 11.5% of patients. The local diagnostic reference levels for the kerma area product were lower than the national Swiss diagnostic reference levels (0.4 Gray [Gy]·cm^2 vs 30 Gy·cm^2 for conventional pacemakers; 0.4 Gy·cm^2 vs 20 Gy·cm^2 for ICDs; 10.2 Gy·cm^2 vs 57 Gy cm^2 for CRTs). Similarly, the local diagnostic reference levels for cumulative dose and fluoroscopy time were below national diagnostic reference levels.

CONCLUSIONS: Local diagnostic reference levels values were far below national diagnostic reference levels. A multicentre approach to assess patient radiation exposure in current practice is strongly desired to establish revised national diagnostic reference levels.

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Introduction

Over the past few decades, interventional electrophysiology has experienced substantial growth, particularly in the realms of ablation procedures and device implantations [1]. The rising adoption and intricacy of imaging and interventional techniques have resulted in higher radiation exposure levels, with cardiologists increasingly contributing to the total cumulative effective radiation dose received by the US population [2]. Fluoroscopy continues to be the primary imaging technique used in the majority of interventional procedures in cardiology [3–5].

Considering these developments, there is growing apprehension about potential health hazards associated with exposure to ionising radiation including stochastic effects (for example radiation carcinogenesis) and tissue reactions (such as skin injuries) [3–7]. In order to mitigate health risks, it is imperative to implement measures aimed at optimising patient radiation exposure and clinical practice as mandated by relevant legislation [3, 8]. One of these measures is clinical radiation audits, which aim to ensure ideal use of ionising radiation in clinical practice [9]. The first clinical radiation audit in a cardiology department in Switzerland took place at our department in 2019. The team of external auditors consisted of a cardiac electrophysiologist, an interventional cardiologist, a medical physicist and an allied professional working in the catheterisation laboratory. By reducing the usage of cine acquisitions, there was a significant reduction in patient radiation exposure for conventional pacemaker implantation [9].

Additionally, national diagnostic reference levels are used to help guide good clinical practice. If patient dose values consistently surpass the established diagnostic reference levels, it is recommended to take corrective actions by assessing and potentially amending practice or the configuration of X-ray systems [3, 7, 10]. Local diagnostic reference levels can also be used to further monitor and optimise lo-

cal practice, as irradiating protocols of radiological devices and training of operators may improve over time.

The aim of this study was to establish local diagnostic reference levels for cardiac implantable electronic device procedures at a tertiary care centre and to compare the local values to the currently available national Swiss diagnostic reference levels.

Methods

We conducted a single-centre retrospective cohort study including all consecutive patients who underwent a cardiac implantable electronic device procedure between October 2018 and October 2020 at University Hospital Zurich. The approval of the ethics committee (BASEC-Nr. 2022-01326) was obtained and the study was conducted in accordance with the ethical standards laid down in the Declaration of Helsinki.

Cardiac implantable electronic device procedures included pacemaker (including leadless), implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy (CRT) implantation, as well as lead extractions / device explantation. We excluded patients who were incorrectly included (for example twice), had their procedure cancelled, underwent a procedure other than those mentioned above (such as subcutaneous ICD implantation or box changes)or where data was missing (figure 1).

In order to establish local diagnostic reference levels, the kerma area product (KAP in Gray [Gy] cm^2), the incident air kerma at the patient entrance reference point ($K_{a,r}$), the fluoroscopy time (t) and the number of cine acquisitions were assessed. $K_{a,r}$, also known as the cumulative dose at the reference point and expressed in milligray (mGy), is the air kerma measured at 15 cm from the isocentre towards the X-ray tube. The isocentre is the midpoint between the X-ray tube and the detector. The reference point corresponds to the point where the X-ray beam enters a medium-sized patient – practically in interventional cardiology, the skin of the patient's back – and is used to estimate patient tissue reactions. t corresponds to the time that the X-ray tube was on and includes the time for fluoroscopy and cine acquisitions. Cine acquisitions are pulsed images produced during the cine runs. All procedures were performed with a biplane cardiology system Artis Q.zen biplane (Siemens Healthcare AG) equipped with two flat-panel detectors 20 cm × 20 cm.

Statistical analysis

Data was collected from a dose management system (DMS, DOSE, Qaelum NV, Belgium) and was cross-checked for accuracy with the patient information system. The primary outcome was patient radiation exposure and was pre-specified. The median values of the overall kerma area product, cumulative dose and fluoroscopy time were set as typical / medical values for different procedures, more specifically pacemakers, leadless pacemakers, ICD, CRT and lead extraction / device explantation, and were used for comparison with national diagnostic reference levels [11]. R studio version 4.2.3 was used to perform all statistical analyses.

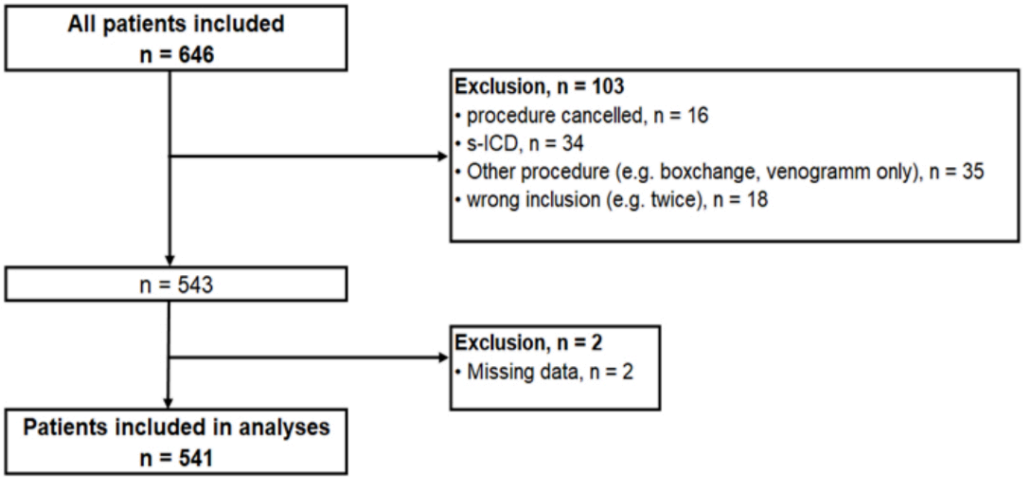
Results

We analysed in total 541 cardiac implantable electronic device procedures. The results of our first analysis were recently published [9] so we hereby present the results focusing on diagnostic reference levels.

The baseline characteristics of the patients included in the study are presented in table 1. The median age was 73 years and 69% were male. 50% of patients underwent pacemaker implantation (including leadless pacemakers), most commonly due to a higher-degree AV block (24.2%). 21.1% of patients received an ICD, 17.2% a CRT and 11.5% underwent lead extraction / device explantation (table 2). The acute procedural success rate and 30-day complications are also shown in table 1. The overall acute procedural success rate was 98.7%. In total, 33 complications (6.1%) were reported within 30 days of the procedure.

Local diagnostic reference levels for the kerma area product, the cumulative dose and the fluoroscopy time are pre-

Figure 1: Patient flowchart shown for the 646 patients included. The reasons for exclusion and the absolute numbers of patients excluded are shown in the boxes on the right. 541 patients were included in the final analysis.



sented for the different types of procedure – pacemakers, leadless pacemakers, ICDs, CRT, and lead extraction / device explantation – in table 3. The currently available national diagnostic reference levels according to the Swiss Federal Office of Public Health (FOPH) [12] are also presented in the same table to facilitate the comparison.

Typical values were used as local diagnostic reference levels. The local diagnostic reference levels for the kerma area product were lower than national diagnostic reference levels (0.4 Gy·cm^2 vs 30 Gy·cm^2 for pacemakers, 0.4 Gy·cm^2 vs 20 Gy·cm^2 for ICDs, 10.2 Gy·cm^2 vs 57 Gy·cm^2 for CRTs, respectively). Similarly, the local diagnostic reference levels for the cumulative dose (in mGy) and the fluoroscopy time (in seconds) were lower than national diagnostic reference levels with 2.7 mGy vs 450 mGy and 265 s vs 600 s for pacemakers; 2.5 mGy vs 418 mGy and 254 s vs 420 s for ICDs; and 1006 s vs 3360 s for CRTs, respectively. National diagnostic reference levels for the implantation of leadless pacemakers and for lead extraction / device explantation are not available yet. No diagnostic reference level values are provided for cine acquisition, for none of the procedures or for the cumulative dose

Table 1:
Baseline characteristics, acute procedural success and 30-day complications shown for all patients. Continuous variables are presented as medians (interquartile range); categorical variables are presented as counts (percentage).

			n = 541
Age (years)			73.0 (61.0–80.3)
Sex: male			372 (68.8%)
BMI (kg/m^2)			26.7 (23.3–29.4)
Medical history	Arterial hypertension		336 (62.1%)
	Dyslipidaemia		349 (64.5%)
	Diabetes mellitus		124 (22.9%)
	Smoking		276 (51.0%)
	Coronary artery disease		240 (44.4%)
	Atrial fibrillation / flutter		236 (43.6%)
	Left ventricular ejection fraction	≥50%	293 (54.2%)
		41–49%	72 (13.3%)
		≤40%	176 (32.5%)
Preprocedural medication	Oral anticoagulation		241 (44.5%)
	Platelet aggregation inhibition		221 (40.9%)
	Beta-blockers		270 (49.9%)
	Antiarrhythmic medication		58 (10.7%)
Acute procedural success			534 (98.7%)
Complications	Total		33 (6.1%)
	Cardiovascular death		3 (0.6%)
	Pneumothorax with chest drain		5 (0.9%)
	Pneumothorax with conservative management		1 (0.2%)
	Haemodynamically relevant pericardial effusion		5 (0.9%)
	Acute heart failure with hospitalisation		5 (0.9%)
	Severe tricuspid regurgitation		2 (0.4%)
	Lead dislocation with revision		10 (1.8%)
	Pocket haematoma with evacuation		1 (0.2%)
	Deep vein thrombosis left arm		1 (0.2%)
	Device infections		0 (0%)

Table 2:
Indication and type of procedure for all patients (n = 541). Values presented as count (percentage).

Indications and procedures		**n**
Indication for pacing	Intermittent higher-degree AV block	131 (24.2%)
	Complete higher-degree AV block	103 (19.0%)
	Sinus node dysfunction	113 (20.9%)
	Bundle branch block and heart failure	69 (12.8%)
Indication for defibrillator	Primary prevention	72 (13.3%)
	Secondary prevention	49 (9.1%)
Pacemaker	Total	153 (28.3%)
	Single chamber	5 (0.9%)
	Dual chamber	148 (27.4%)
Leadless pacemaker	Total	119 (22%)
Implantable cardioverter defibrillator (ICD)	Total	114 (21.1%)
	Single chamber	68 (12.6%)
	Dual chamber	46 (8.5%)
Cardiac resynchronisation therapy (CRT)	Total	93 (17.2%)
	CRT-P	35 (6.5%)
	CRT-D	58 (10.7%)
Lead extraction/ device explantation		62 (11.5%)

for CRT implantations. The local diagnostic reference levels for cine acquisitions were 10 images for pacemaker and 100 for leadless pacemakers, 6 images for ICD, 171 images for CRT and 121 images for lead extraction / device explantation.

Discussion

This retrospective cohort study assessed patient radiation exposure during device procedures by establishing local diagnostic reference levels and comparing them with the national diagnostic reference levels.

The local diagnostic reference levels for kerma area product, cumulative dose and fluoroscopy time during pacemaker, implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy (CRT) implantations were notably far below the currently available national diagnostic reference levels established by the Federal Office of Public Health in 2018 [12]. This suggests that national diagnostic reference levels need to be updated more regularly, e.g. every 3 to 5 years. In comparison to current literature, the local diagnostic reference levels set at our institution for kerma area product during pacemaker / ICD implantations were lower than those reported in recent studies, with the kerma area product ranging from 2.0 to 20.9 Gy·cm^2 in recent studies from other groups. Similarly, the kerma area product for CRT implantations varied from 7.7 to 40.9 Gy·cm^2 [13–15]. The local diagnostic reference levels for fluoroscopy time during pacemaker / ICD implantations and CRT implantations were similar to the fluoroscopy time presented in a large retrospective study on 2055 device implantations conducted in Italy over a 7-year period [13].

Regarding patient radiation exposure during lead extraction / explantation, information in the literature is scarce [16]. For leadless pacemakers, our results extend and corroborate the findings of an observational study from two tertiary electrophysiology referral centres in Switzerland. However, national diagnostic reference levels for leadless pacemaker implantations have not yet been established by the Federal Office of Public Health since this is a rather novel technology. It is important that pacemaker implantations are clearly distinguished by device type, as leadless pacemakers often need longer fluoroscopy time and radiation exposure than conventional pacemakers due to the different access (mostly femoral) and differences in implant procedure.

We observed low patient radiation exposure during cardiac implantable electronic device interventions. We attribute this to optimised operator practices and evolving technology since the publication of the national diagnostic reference levels. First, we try to minimise the number of cine acquisitions as the related radiation dose typically exceeds the fluoroscopy dose by 10 times [3]. Additionally, protocols are by default set at 3 frames per second and we only use higher frame rates if the interventionists need better temporal resolution. This aligns with the results of a retrospective study involving 495 patients, showing that the reduction of the frame rate by half led to a 62% decrease in radiation dose during device procedures [14]. Our results confirmed that our goal should remain to minimise cine usage as much as possible. Furthermore, continuous education of personnel on optimising patient exposure by using a low frame rate and acquiring the fewest possible cine images help keep the radiation doses at low levels. Thus, setting national diagnostic reference level values for cine acquisitions during cardiac implantable electronic device procedures is essential.

To mitigate information bias, data was checked thoroughly, with two patients having to be excluded due to missing data. Performed procedures were heterogeneous and varied in complexity, making the establishment of diagnostic reference levels more challenging, however more representative. We recognise that data obtained solely from a single centre may lack representativeness as a standard. A multicentre approach to assess patient radiation exposure is strongly desired to establish revised national diagnostic reference levels.

Conclusions

Local diagnostic reference levels helped to increase awareness and review local practices for improvements in patient and operator protection. Regarding diagnostic reference levels, local values were far below the national diagnostic reference levels, which suggests that national diagnostic reference levels need to be updated more regularly to take into account the optimised protocols as well as new types of procedures.

Table 3:
Local and national diagnostic reference levels for the different types of procedures. Median values (typical values) are used as local diagnostic reference levels (LDRLs). The data is presented as median (IQR); outliers beyond the three standard deviation intervals were removed.

Type of procedure	Kerma area product (KAP in Gray·cm^2)		Cumulative dose (mGy)		Fluoroscopy time (s)	
	Local values: median (IQR)	National diagnostic reference levels	Local values: median (IQR)	National diagnostic reference levels	Local values: median (IQR)	National diagnostic reference levels
Pacemaker	0.4 (0.3–0.6)	30	2.7 (1.6–4.2)	450	265.0 (190.5–386.0)	600
Implantable cardioverter defibrillator (ICD)	0.4 (0.2–0.8)	20	2.5 (1.3–5.3)	418	253.5 (172.2–372.0)	420
Cardiac resynchronisation therapy (CRT)	10.2 (5.7–20.3)	57	113.8 (57.5–258.6)	–	1006.0 (689.0–1423)	3360
Lead extraction / device explantation	3.5 (0.7–10.9)	–	28.5 (4.0–94.3)	–	390.0 (148.0–755.5)	–
Leadless pacemaker	6.3 (3.7–13.2)	–	52.3 (29.4–93.7)	–	232.0 (161.5–388.0)	–

Data sharing statement

The data that support the findings of this study is available in anonymised form from the corresponding author, AS, upon reasonable request.

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Potential competing interests
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