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DEVICES

Radiation exposure during cardiac device implantation: Lessons learned from a multicenter registry

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Abstract

Background: Little data are available about radiation exposure during cardiac electrical device implantation, and no dose reference levels have been published. This multicenter, prospective, observational study assesses patient and staff radiation exposure during cardiac device implantations, and aims at defining dose reference levels.

Methods: Patient demographic, procedural, and radiation data were obtained for 657 procedures from nine institutions. Physician and staff exposure were measured using real-time dosimeters worn beneath and above lead apron. Statistical analysis included fluoroscopy time (FT), dose-area product (DAP), and DAP adjusted for FT and body mass index.

Results: Pacemakers and cardioverter defibrillators were implanted in 481 and 176 patients, respectively. Of these, 152 were treated with cardiac resynchronization therapy (CRT). Median FTs were 837s (interquartile range [IQR]: 480-1323), 117s (IQR: 69-209), and 101s (IQR: 58-162), and median DAPs were 1410 (IQR: 807-2601), 150 (IQR: 72-338), and 129 (IQR: 72-332) cGy.cm^2 for biventricular, dual chamber, and ventricular device implantation, respectively. Dose reference levels correspond to the third quartile values. During CRT, higher exposure was observed with four X-ray systems than with the two newer and customizable ones (adjusted DAP of 0.90 [IQR: 0.26-1.01] and 0.29 [IQR: 0.23-0.39], respectively; $P < .001$).

Conclusion: Based on real-life measurements, this multicenter registry provides dose reference levels and may help centers assess radiation exposure. Although biventricular device implantation was responsible for the highest radiation exposure, FT was meaningfully shortened compared to previously reported values. For a same FT, the use of new generators and custom settings has significantly reduced DAP.

KEYWORDS

cardiac resynchronization therapy, defibrillators, implantable, radiation exposure, radiation monitoring

1 | BACKGROUND

Patient exposure to X-rays during cardiac interventions is high and may have deleterious effects, including an increased risk of developing cancer.[1] Unlike most diagnostic procedures using ionizing radiation, dose reference levels in cardiology for coronary angioplasty have only recently been established from multicenter studies.[2] The complexity of cardiac rhythm device implantations is steadily increasing,

but there are little data on radiation exposure. Despite the relatively low radiation exposure associated with these implantations, the procedures should still be performed in accordance with the as low as reasonably achievable principle. They should comply with the most recent procedural guidelines,[3–6] in order to improve the radiation protection of patients and staff in operating rooms. The Heart Rhythm Society and the European Heart Rhythm Association reviewed current methods used to reduce radiation exposure.[7,8] No reference level is currently available in the literature, as all published studies come from single centers.

Due to the increased complexity of cardiac resynchronization therapy (CRT), the duration of operations may be extended,[9,10] resulting in increased fluoroscopy times (FTs). Moreover, occupational exposure has not been assessed in the literature, whereas the risk to medical staff appears to be significant.[11–14]

Nonfluoroscopic mapping systems with electromagnetic guidance[15–18] or new shielding equipment[19] result in dose reduction, but they are not commonly used. Improvements in X-ray generator software, the use of low frame rate fluoroscopy, new generators, and recent technological advances in coronary sinus leads have been shown to reduce radiation exposure,[20–26] particularly in young patients.[27] The objectives of this study were to describe current radiation protection practices during the implantation of cardiac devices, define dose reference levels, and assess radiation exposure based on the devices currently in use.

2 | METHODS

2.1 | Study design

The Ray' Pace study was a prospective multicenter registry of first-line device implantation procedures performed in nine hospitals. Centers were invited to participate if they met the following conditions: availability of an X-ray equipment with a dose-area product (DAP) measuring device; two real-time dosimeters for the physician; well-trained physicians with experience in at least 300 current cardiac rhythm device implantations; and, for CRT, at least 50 procedures as a first operator (Supporting Information).

Patient demographics including age and body mass index (BMI) were collected as part of the clinical routine. Procedural data included the clinical indication of the device implantation, the implantation site (left or right), X-ray equipment and parameters, the use of oblique projection, collimation, radiation protection screen, and the duration of procedures. Any difficulties that resulted in a major increase in radiation exposure were asked to be described.

The dose delivered to the patient was assessed by recording FT and DAP, as indicated by the equipment at the end of the procedure. DAP is defined as the absorbed dose multiplied by the irradiated area, expressed in centigray-centimeters squared (cGy·cm^2). Exposure of physicians and staff was measured using real-time electronic silicon diode dosimeters (unit: μSv). The operators wore two dosimeters on the collar, one beneath the lead apron as usual and the other above the apron. The nurses wore a dosimeter under the lead apron.

2.2 | Ethics and consent

The study complies with the Declaration of Helsinki. The research protocol was approved by the local ethics committee, and the informed consent of the subjects (patients and operators) was obtained.

2.3 | Equipment

Seven different X-ray imaging systems were used: OEC 9900 Elite and OEC Fluorostar 7900 (General Electric Medical Systems, Milwaukee, WI, USA), ARCADIS Varic and Siremobil Compact L (Siemens AG, Munich, Germany), BV Pulsera and Integris V5000 (Philips Medical Systems, Eindhoven, The Netherlands), and XTP 8100G (Toshiba, Tokyo, Japan). Custom settings were available for some of the newer generators (less than 5 years old, Siemens Arcadis and Philips Pulsera), used in some centers. In accordance with the national quality control protocol, established in 2005, all X-ray equipment in France must be inspected annually to ensure compliance with technical requirements and tolerances for patient dosimetry and image quality. These include an assessment of high contrast spatial resolution in different magnification modes, the maximum allowable patient entrance dose, the accuracy of the display of DAP measuring devices, and the accuracy of X-ray generator parameters (kV and mA reproducibility). Therefore, no specific or additional quality control of the equipment was required before the start of the study.

2.4 | Reference levels

Dose reference levels have been used and defined in accordance with international guidelines. In this study, the reference values for each radiation dose parameter were set as the third quartile (75th percentile) of the total distribution.

2.5 | Statistical analysis

Descriptive analysis and pairwise correlation plots between DAP and FT were used to detect extreme and outliers. They were validated and/or corrected by each center concerned before the final analysis. Summary values are given as median and interquartile range (IQR). Continuous data, such as DAP, FT, and DAP/FT ratio, were log-transformed for multivariable linear regression or linear correlation analyses. In order to rule out the role of BMI in patient receiving high level radiation doses, $\frac{DAP \times 10}{BMI \times FT}$ was used. Kruskal-Wallis test was used for the comparisons.

3 | RESULTS

3.1 | Patients and procedures

Between February 2013 and September 2013, data from a total of 657 patients (229 female) were registered. Patient and procedural characteristics are summarized in Table 1. Mean patient BMI was 26.7 ± 4.7 kg/m^2. One hundred and thirty-five patients (21%) had a BMI greater than 30 kg/m^2, the obesity criterion. The procedures

TABLE 1 Patient characteristics per procedure

	All patients	Single chamber PM	Dual chamber PM	Single chamber ICD	Dual chamber ICD	CRT-P	CRT-D	
	n = 657	n = 73	n = 347	n = 46	n = 39	n = 61	n = 91	*P*-value
Median age, years (IQR)	78 (69-85)	84 (79-89)	80 (72-86)	63 (53-73)	65 (58-77)	81 (77-85)	70 (65-76)	<.001
Male, n (%)	428 (65%)	45 (62%)	205 (59%)	40 (87%)	32 (82%)	38 (62%)	68 (75%)	<.001
Median BMI (IQR), kg/m^2	26 (24-29)	25 (23-28)	26 (23-29)	26 (23-29)	25 (24-28)	27 (24-30)	27 (25-30)	.004
BMI > 30 kg/m^2, n (%)	135 (21%)	11 (15%)	69 (20%)	10 (22%)	6 (15%)	14 (23%)	25 (27%)	.416

Abbreviations: PM, pacemaker; ICD, defibrillator; CRT-P, biventricular pacemaker; CRT-D, biventricular defibrillator; IQR, interquartile range; BMI, body mass index.

consisted of cardiac implantation of 481 pacemakers and 176 defibrillators (68% left-sided), including 152 CRT devices (40% of biventricular pacemaker and 60% of biventricular defibrillator). Difficulties occurred in 73 patients, mainly related to coronary sinus lead implantation (36 patients, 49%) but also for other reasons (10 subclavian venous access, 11 right-sided leads, eight unusual anatomies, three device pocket revisions, one cephalic venous dissection, one atrial tachycardia, one previous lead extraction, one venous occlusion, and one high venous pressure). Implantation of a left ventricular lead in a coronary sinus branch for CRT failed in two patients (1.3%).

3.2 | Radiation protection methods

A lead apron with a thickness of 0.25 mm, 0.35 mm, and 0.50 mm was worn by physicians in 51%, 14%, and 35% of the procedures, respectively (all with a double front layer). A face shield was used in 32% of the procedures. To reduce radiation exposure, five centers used customized X-ray generator parameters. The lowest possible image acquisition, according to the operator's needs, was adjusted to minimize FT. Collimation was applied in 72% of the procedures. In addition to the anterior to posterior projection, the left anterior oblique projection was used in 47% of the procedures. Fluoroscopy with a pulse rate of less than 12 fps and continuous X-ray were used in 85% and 15% of the procedures, respectively.

3.3 | Dose delivered to the patient and received by medical staff

Because radiation exposures were similar when pacemakers or defibrillators were implanted, the data obtained with these devices were analyzed in a single variable. The results of radiation exposure during single and dual chamber implantation and CRT are presented in Table 2. CRT procedures showed the longest FT, the highest DAP, and doses received by physicians and staff (837 s [IQR: 480-1323], 1410 cGy.cm^2 [IQR: 807-2601], 0.09 µSv [IQR: 0.01-0.06], and 0.08 µSv [0.01-0.26], respectively).

The DAP data from the six centers that reported more than 10 CRT are presented in Figure 1. The observed reference level (third quartile) was 2600 cGy.cm^2.

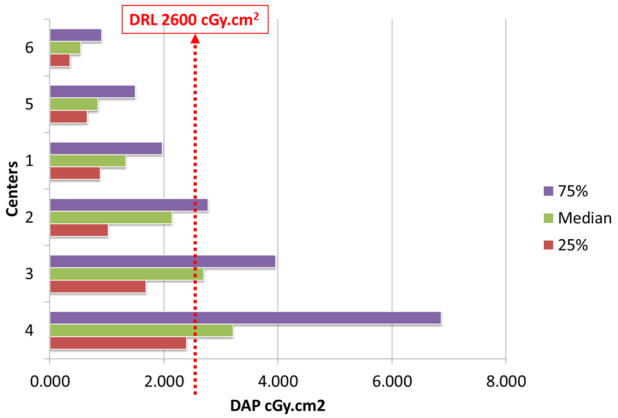

FIGURE 1 Patient radiation exposure during CRT procedures: results from the six centers with the highest number of procedures (median, first and third quartiles)
Abbreviation: DRL, dose reference level. [Color figure can be viewed at wileyonlinelibrary.com]

3.4 | X-ray equipment

Radiation exposure data were quite different from one type of X-ray generator to another, as shown by the differences observed among centers for the adjusted DAP (Figure 2). Procedural data (eg, use of collimation, number of device implanted) were examined to explore these differences. No significant relationships were found. The adjusted DAP ($\frac{DAP \times 10}{BMI \times FT}$) was lower for the CRT performed with Siemens *Arcadis* and Philips *BV Pulsera* in two centers, compared to older models used in four centers (0.27 [IQR: 0.19-0.36], 0.32 [IQR: 0.26-0.40], and 0.90 [IQR: 0.56-1.01], respectively, $P < .001$). Log-transformed adjusted DAP for each generator is shown in Figure 3.

4 | DISCUSSION

Previously, radiation exposure during implantation of cardiac electronic devices was low because FTs were minimal.[28] This is no longer the case since the widespread use of resynchronization. Patients and healthcare teams are now exposed to a significant risk of radiation

TABLE 2 Dose delivered to patients and personal dose equivalent received by physician and staff

	All	Ventricular	Dual chamber	CRT	
	n = 657	n = 119	n = 386	n = 152	*P*-value
Median fluoroscopy time (IQR), second	145 (79-384)	101 (58-162)	117 (69-209)	837 (480-1323)	<.001
Median DAP (IQR), cGy.cm^2	218 (90-700)	129 (72-332)	150 (72-338)	1410 (807-2601)	<.001
Number of patients with DAP > 400 cGy.cm^2 (%)	236 (35%)	22 (18%)	77 (19%)	137 (90%)	<.001
Median Hp(10), physician dosimeter outside the lead apron (IQR), µSv	4.6 (1.0-18.3)	2.7 (0.5-9.9)	3.0 (0.9-8.0)	28.0 (10.3-67.6)	<.001
Median Hp(10), Physician dosimeter under the lead apron (IQR), µSv	0.06 (0.01-0.16)	0.06 (0.01-0.09)	0.06 (0.01-0.14)	0.09 (0.01-0.60)	<.001
Median Hp(10), Staff dosimeter under the lead apron (IQR), µSv	0.12 (0.08-0.20)	0.11 (0.06-0.17)	0.11 (0.06-0.19)	0.19 (0.14-0.26)	<.001

Note. Patient effective dose is an assessment for the whole body = equivalent dose × tissue weighting factor.
Abbreviations: IQR, interquartile range; DAP, dose-area product; Hp(10), personal dose equivalent.

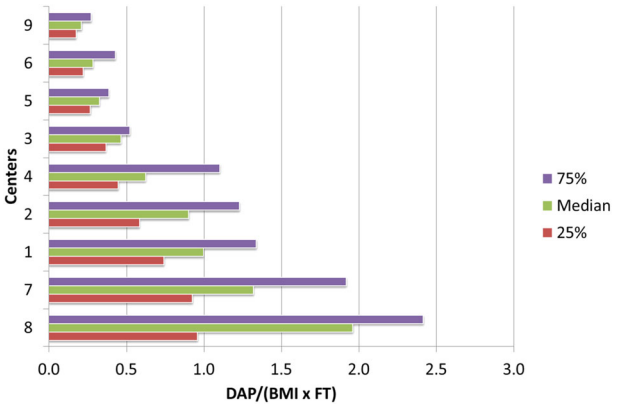

FIGURE 2 Measurement of radiation dose with the adjusted DAP ($\frac{DAP}{BMI \times FT}$) in dual or ventricular device implantation: results by center (median, first and third quartiles) [Color figure can be viewed at wileyonlinelibrary.com]

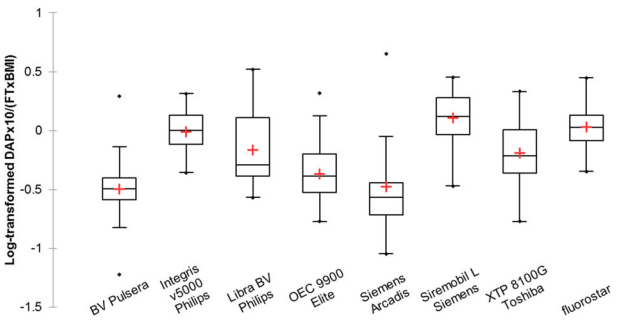

FIGURE 3 Comparison of radiation dose among generators: distribution of log-transformed $\frac{DAP \times 10}{BMI \times FT}$ per generator for single and dual chamber procedures [Color figure can be viewed at wileyonlinelibrary.com]

exposure. The most recent studies have shown a reduction in the delivered dose, but this dose remains high.[7]

Good practice recommendations cannot be derived from these studies because radiation measurements are difficult to interpret in the absence of details on aggravating factors (such as BMI), and when the data are based on averages that have no statistical value in the field of radiation. Our study provides comprehensive data from experienced teams (as evidenced by the high success rate of ventricular resynchronization) that are used to determine reference levels with sufficient reliability. It also points out that FT does not summarize all radiation exposure risks, and should not be the only dose reduction indicator used by practitioners.

Based on the results of this multicenter study, we propose dose reference levels, in particular for resynchronization procedures with a value of 2600 cGy.cm^2 (third quartile). This reference can be used by interventional cardiac wards to assess and ensure the quality of equipment and practices, and to issue an alert in the event of significant radiation exposure.

It is likely that equipment evolution will further improve these values in the future. The comparison between devices confirms that some of the newer devices further reduce the dose. This is consistent with the modern evolution of equipment and operator experience. The significant reduction in radiation exposure observed with recent generators, allowing fine tuning, is not negligible and encourages us to continue along this path.[3] In this respect, it seems that the use of collimation is not yet fully widespread, although it is recommended.

Measuring the dose directly received by doctors and staff provides a better understanding of the risk involved: operators are exposed by the proximity of the patient and scattered radiation, but our study shows that the healthcare team receives a minimal dose.

By comparing the practices identified in our study with those reported in the survey conducted by the European Heart Rhythm Association,[8] the results are similar for the proportion of use of pulsed fluoroscopy with low pulse rate. This technique was applied by 85% of the participant in our study compared to 70% of European centers. The recommended limit of 60 min of radioscopy has only been exceeded in two of our patients, so it remains exceptional as in the European survey. Collimation of the X-ray beam was used by 91% of the European centers that did not report whether they apply it to all patients. In our study, only 72% of the patients benefited from collimation, while all

the centers reported using it. The daily application of the recommendations remains inconsistent, even if medical teams believe they are being followed.

Although the mean values are difficult to interpret for this type of variable, the second European survey[7] has reported an average irradiation in resynchronization procedures of 21.6 mGy.m^2, well above the value of 1.99 mGy.m^2 reported in our study, while the FT was similar (16 and 18 min, respectively). The lack of customized parameter for the X-Ray generators is probably the reason. Despite the recommendations in this regard and as observed in this study, practices have not improved sufficiently over time.

On the other hand, our favorable results in reducing median DAP using customized parameters are encouraging, as also shown by the latest published studies assessing the effect of new technologies dedicated to dose reduction.[20–26]

5 | LIMITATIONS OF THE STUDY

The procedures were performed by a relatively small number of experienced operators, as evidenced by the high success rate of coronary sinus lead implantation. The reference values may not apply to less experienced operators. The power of the statistical analysis in CRT procedures is limited by the low number of procedures performed by three centers (less than 10 during the study).

6 | CONCLUSION

The Consensus Statements of the Heart Rhythm Society Experts and the guidelines of the European Heart Rhythm Association emphasized the need for diagnostic reference levels, but they have not yet been defined for complex and specific procedures such as cardiac device implantation. The availability of a dose reference level should help cardiologists to improve their practices in order to reduce patient and physician exposure to radiation, particularly in CRT procedures.

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AUTHOR CONTRIBUTIONS

PB was associated with concept/design, data collection, data analysis/interpretation, drafting article, and critical revision and approval of the article. AD, WA, GH, GG, PS, MS, CM, and JT were associated with data collection and approval of the article. JB contributed in statistics, data analysis/interpretation, and critical revision and Approval of the article. AM and contributed in concept/design, data collection, data analysis/interpretation, and critical revision and approval of the article.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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