ORIGINAL RESEARCH

X-Ray Exposure in Cardiac Electrophysiology: A Retrospective Analysis in 8150 Patients Over 7 Years of Activity in a Modern, Large-Volume Laboratory

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***Background*—**Only a few studies have systematically evaluated fluoroscopy data of electrophysiological and device implantation procedures. Aims of this study were to quantify ionizing radiation exposure for electrophysiological/device implantation procedures in a large series of patients and to analyze the x-ray exposure trend over years and radiation exposure in patients undergoing atrial fibrillation ablation considering different technical aspects.

***Methods and Results*—**We performed a retrospective analysis of all electrophysiological/device implantation procedures performed during the past 7 years in a modern, large-volume laboratory. We reported complete fluoroscopy data on 8150 electrophysiological/device implantation procedures (6095 electrophysiological and 2055 device implantation procedures); for each type of procedure, effective dose and lifetime attributable risk of cancer incidence and mortality were calculated. Over the 7-year period, we observed a significant trend reduction in fluoroscopy time, dose area product, and effective dose for all electrophysiological procedures ($P<0.001$) and a not statistically significant trend reduction for device implantation procedures. Analyzing 2416 atrial fibrillation ablations, we observed a significant variability of fluoroscopy time, dose area product and effective dose among 7 different experienced operators ($P<0.0001$) and a significant reduction of fluoroscopy use over time ($P<0.0001$) for all of them. Considering atrial fibrillation ablation techniques, fluoroscopy time was not different ($P = 0.74$) for radiofrequency catheter ablation in comparison with cryoablation, though cryoablation was still associated with higher dose area product and effective dose values ($P<0.001$).

***Conclusions*—**Electrophysiological procedures involve a nonnegligible x-ray use, leading to an increased risk of malignancy. Awareness of radiation-related risk, together with technological advances, can successfully optimize fluoroscopy use. **(*J Am Heart Assoc*. 2018;7:e008233. DOI: 10.1161/JAHA.117.008233.)**

Key Words: atrial fibrillation • catheter ablation • x-ray

Over the past 20 years, the growing number of electrophysiological (EP) procedures and device implantations (DIs) has caused increased concern over potential radiation risk effects.[1] Fluoroscopy imaging involves a nonnegligible exposure to ionizing radiation for both patients and electrophysiology laboratory personnel, depending on laboratory workload and the complexity of the procedures.[2] Effects of exposure to ionizing radiation include deterministic and stochastic effects. The latter is particularly relevant in young patients, as a consequence of their higher radiosensitivity and

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An accompanying Table S1 is available at http://jaha.ahajournals.org/content/7/11/e008233/DC1/embed/inline-supplementary-material-1.pdf

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Clinical Perspective

What Is New?

- Comprehensive fluoroscopy data (fluoroscopy time, dose-area product, effective dose) for electrophysiological procedures are reported in a large "real-life" electrophysiological population.
- An assumption for the lifetime attributable risk was assessed.
- The analysis of the x-ray use in 7 experienced operators performing AF ablation showed an overall significant difference in fluoroscopy use among them.

What Are the Clinical Implications?

- Awareness and culture of radiation-related risk and technological advances can successfully optimize fluoroscopy use.

longer life span, and in patients undergoing long, complex, or repeated procedures because of cumulative high radiation doses.[3–8] On the other hand, the total exposure also may lead to a significant cumulative dose and lifelong radiation risk to the electrophysiology staff.[9,10] For this reason, the European Directives and the International Commission on Radiological Protection recommend that physicians should be guided by the diagnostic reference levels for an appropriate use of radiation.[11]

Recently, the major cardiovascular societies have published recommendations about x-rays use in interventional cardiology and suggested practical ways to reduce them.[12–14] This can be achieved by raising operator awareness, optimizing the technical settings of the x-ray system, or using a 3-dimensional electroanatomic mapping (EAM) system.

However, to date, there are few data evaluating in a systematic way fluoroscopy time, dose exposure in terms of dose area product (DAP), radiation-related risk evaluated by effective dose (ED) and lifetime attributable risk of cancer incidence in patients undergoing EP/DI procedures. Furthermore, diagnostic reference levels for EP/DI procedures have not yet been proposed.

The aims of this study are: (1) to quantify ionizing radiation exposure for all types of EP/DI procedures in a large series of patients; (2) to analyze the x-ray exposure trend over the years, considering that no institutional changes and/or recommendations about fluoroscopy use were performed and operators are free to use fluoroscopy according to their sensitivity; and (3) to analyze radiation exposure in patients undergoing atrial fibrillation (AF) ablation considering the ablation technique, redo procedures, preprocedural computed tomographic (CT) scan and the experience of operators.

Finally, based on our results, we propose and promote the use of updated diagnostic reference levels for EP/DI procedures, as they are an important reference for every electrophysiology laboratory to compare itself with the present standard.

Methods

This is a retrospective study conducted at the Heart Rhythm Center at Centro Cardiologico Monzino IRCCS, Milan, Italy. The Institutional Review Board approved the study. All patients gave a generic written consent for scientific purposes. The data, analytic methods, and study materials will be made available to other researchers for purposes of reproducing the results or replicating the procedure. The data that support the findings of this study are available from the corresponding author on request.

The electrophysiology database of our institution was reviewed to identify all patients who underwent EP and DI procedures between January 2010 and December 2016.

Electrophysiological procedures included EP studies, catheter ablation of supraventricular tachycardia, atrial flutter and atrial tachycardia, AF, premature ventricular contractions, ventricular tachycardia.

DI included implantation of a permanent pacemaker or cardioverter-defibrillator and cardiac resynchronization therapy devices.

Demographic, clinical, and procedural data were collected, including age, sex, type of electrophysiological procedure, fluoroscopy time, and DAP incurred to the patient. In the case of atrial fibrillation ablation patients, we also took into account history of previous AF ablation procedures, ablation technology used, preprocedural CT scan, and first operator's experience. Only cases with availability of all clinical, procedural, and fluoroscopic data were included in the study.

All procedures were performed by 12 operators routinely working at the Center; of these, 7 operators performing at least 50 AF procedures per year in the past 10 years were considered experienced AF ablation operators.[11] Because our institution has a cardiology fellowship training program, all procedures entailed some degree of fellow education involving catheter manipulation.

During this 7-year period, no institutional changes or recommendations about fluoroscopy use were made, but operators, according to their sensitivity and x-ray awareness, have adapted their method of working.

The procedures were performed in 3 different electrophysiology rooms; in all 3 rooms, x-ray imaging was performed using a GE Innova 2100IQ (General Electric Healthcare) with total filtration of 3 mCu, and anodic angle of 120°. The screening fluoroscopy was routinely performed at the factory low setting of 7.5 pulses per second, pulse length of 6 ms, field of view of 20 cm, energy per frame of 70 to 80 kV, no collimation, and with the secondary radiation grid in situ.

Because of the necessity of image storing, we stored the last fluoroscopy image in most cases, while we used angiography only in selected cases (ie, cryoablation, cardiac resynchronization therapy, and epicardial ventricular tachycardia ablation). When used, angiography images were acquired with the following settings: 15 pulses per second, pulse length of 7 ms, field of view of 20 cm, energy per frame of 90 kV, and no collimation.

DAP was measured using the inbuilt DAPmeter (DIAMENTOR®; M4-KDK DAP/Dose Meter, PTW, Freiburg, Germany), and it was expressed in centigray×cm^2 (cGy×cm^2).

The malignancy risk attributable to radiation exposure during the electrophysiological procedures was evaluated by the calculation of the mean ED with the formula: mSv=DAP (Gy×cm^2)×0.20 for men, mSv=DAP (Gy×cm^2)×0.20×1.38 for women; 0.40 should be used instead of 0.20 in patients that are <15 years old.[14]

Furthermore, an assumption for the lifetime attributable risk of cancer incidence and mortality was estimated multiplying the ED that each patient received with the standardized Biological Effects of Ionizing Radiation VII conversion factor of 0.0001/mSv.[15]

Technical Features

All complex electrophysiological procedures (ie, AF or atypical atrial flutter ablation, ventricular tachycardia or premature ventricular contraction ablation) were performed using 1 of 2 different nonfluoroscopic 3-dimensional electroanatomic mapping systems available at our center: Carto™ (Biosense Webster, CA, USA) or EnSite-NavX™ (Abbott, MN, USA). In the case of AF ablation, different technologies were routinely used: manual radiofrequency catheter ablations; cryoablation (Arctic Front™ and Arctic Front Advance™; Medtronic, Minneapolis, MN, USA); and robotic catheter ablations (Hansen Medical, Mountain View, CA, USA). An intracardiac echocardiogram (AcuNav, Siemens Healthcare, USA; or ViewFlex, Abbott, Toms River, NJ, USA) was used in all ventricular tachycardia ablations and in selected cases of AF ablation.

For supraventricular tachycardia, a 3-dimensional electroanatomic mapping system was used only in selected cases in order to obtain a minimal fluoroscopic approach. All other procedures were performed with fluoroscopy only.

Statistical Analysis

All outcome measures were skewed by continuous variables; therefore, nonparametric tools were used. Standard descriptive statistics were used to summarize the data and expressed as median (with range or interquartile range).

Differences in measures of radiation exposure across procedural and interventional types were tested using the Kruskal-Wallis test (nonparametric analog of ANOVA), and then further compared after adjustment using linear regression.

Correlations between variables were determined using *P* trends of variation from 2010 to 2016 were assessed by the analysis of covariance (ANCOVA).

All statistical analyses were performed using SPSS v.22 and SAS 9.4. Statistical significance was established a priori at a 2-tailed $P<0.05$.

Results

Between January 1, 2010, and December 31, 2016, a total of 7795 EP procedures and 2805 DIs were performed in our center. All clinical, procedural, and fluoroscopic data were available on 8150 procedures that constituted the study population.

Overall study population consisted of 2416 AF ablations (mean age 60±11; 74% male); 468 atrial flutter or atrial

Table 1. Study Population Distribution Over the 7-Year Study Period

	2010	2011	2012	2013	2014	2015	2016	7 Years
AF	245	274	290	364	339	442	462	2416
AFl/AT	34	73	49	71	57	96	88	468
SVT	127	128	122	129	136	167	170	979
VT	53	57	43	80	66	82	72	453
PVC	52	40	49	61	71	78	99	450
EPS	151	205	105	185	133	276	274	1329
PM/ICD	102	125	138	248	245	438	447	1743
CRT	10	31	31	38	52	63	87	312
All procedures	774	933	827	1176	1099	1642	1699	8150

AF indicates atrial fibrillation; AFl, atrial flutter; AT, atrial tachycardia; CRT, cardiac resynchronization therapy devices; EPS, electrophysiology studies; ICD, implantable cardioverter defibrillator; PM, pacemaker; PVC, premature ventricular contractions; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

tachycardia ablations (mean age 60±16; 74% male); 979 supraventricular tachycardia ablations (mean age 45±18; 44% male; 113 procedures were performed according to a minimal fluoroscopic approach); 453 ventricular tachycardia ablations (mean age 61±16; 89% male); 450 premature ventricular contraction ablations (mean age 47±17; 64% male); 1329 EP studies (mean age 54±19; 69% male); 1743 permanent pacemaker/cardioverter-defibrillator implantations (mean age 74±12; 67% male); and 312 cardiac resynchronization procedures (mean age 70±10; 76% male).

Table 1 summarizes study population distribution over the 7-year study period.

Fluoroscopy exposure data for the study population are summarized in Table 2. In the same table, the estimated lifetime attributable cancer risk is calculated. For example, in our population, a patient who underwent an AF ablation had a potential increased cancer risk of 0.16% over the base rate risk; that means that there is potentially an excess of 160 cancers observed in a population of 100 000 treated patients.

Overall, our fluoroscopy data results were comparable to fluoroscopy exposure reported in the literature. In Table S1, we report a brief nonsystematic review of available data regarding fluoroscopy use and dose, considering only studies with at least 50 patients and that reported either DAP or ED.

Fluoroscopy Exposure Data Over Time

Fluoroscopy use and radiation exposure data for different EP/DI procedures were analyzed over time (Table 3). A fluoroscopy exposure trend was calculated showing a significant reduction ($P<0.0001$) in fluoroscopy time and DAP and ED values for AF, atrial flutter/atrial tachycardia, supraventricular tachycardia, ventricular tachycardia, premature ventricular contraction ablation, and electrophysiological studies (ED–electrophysiological studies: $P = 0.02$), while a not significant consensual reduction in all exposure values was observed for both permanent pacemaker/cardioverter-defibrillator and cardiac resynchronization device implantation procedures.

Fluoroscopy Exposure in AF Ablation Procedure

Analysis according to operators

Seven different experienced electrophysiology operators (>50 procedures per year in the past 10 years) were compared in order to evaluate the differences in the use of x-rays over the course of 7 years. Overall, there was a significant variability ($P<0.0001$) of fluoroscopy time, DAP, and ED values among operators (Table 4).

Interestingly, over 7 years of activity, all the operators significantly decreased ($P<0.0001$) the use of x-rays with

Table 2. Fluoroscopy Exposure Data

	AF (n=2416)	AFl/AT (n=468)	SVT (n=979)	VT (n=453)	PVC (n=450)	EPS (n=1329)	PM/ICD (n=1743)	CRT (n=312)
Fluoroscopy time, min	23 (15–35)	14 (7–24)	13 (6–21)	36 (24–49)	13 (7–22)	2 (0.5–5)	4 (2.5–7.0)	17 (11–29)
DAP, cGy×cm^2	7373 (3735–13 628)	3231 (1381–6958)	1721 (727–3884)	13 849 (5606–23 429)	2609 (925–6178)	347 (148–882)	545 (257–1181)	4094 (2028–8210)
Effective dose, mSv	16.0 (8.2–28.8)	7.3 (3.1–14.7)	4.1 (1.8–9.1)	28.4 (11.7–47.7)	6.2 (2.1–13.5)	0.8 (0.3–2.0)	1.2 (0.6–2.6)	8.7 (4.7–17.1)
LAR, %	0.16 (0.08–0.29)	0.07 (0.03–0.15)	0.04 (0.02–0.09)	0.28 (0.12–0.48)	0.06 (0.02–0.14)	0.008 (0.003–0.02)	0.01 (0.006–0.026)	0.09 (0.04–0.17)

For SVT ablation, 113 (12%) procedures were performed with a 3-dimensional electroanatomic mapping system to obtain a minimal fluoroscopic approach. AF indicates atrial fibrillation; AFl, atrial flutter; AT, atrial tachycardia; CRT, cardiac resynchronization therapy devices; DAP, dose area product; EPS, electrophysiology studies; ICD, implantable cardioverter defibrillator; LAR, lifetime attributable risk; PM, pacemaker; PVC, premature ventricular contractions; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

Table 3. Fluoroscopy Use and Radiation Exposure Over Time

		Fluoroscopy Time (Min)		DAP (cGy×cm^2)		Effective Dose (mSv)	
AF	2010	45 (32–64)	*P* trend <0.0001 Δ = −59%	16 213 (9466–26 732)	*P* trend <0.0001 Δ = −74%	34.0 (19.9–58.2)	*P* trend <0.0001 Δ = −73%
	2011	39 (27–51)		13 011 (7673–21 449)		28.3 (16.9–46.4)	
	2012	28 (20–37)		11 217 (6411–17 197)		24.2 (13.8–37.1)	
	2013	24 (17–31)		7821 (4750–13 357)		16.9 (10.1–28.2)	
	2014	20 (14–27)		6565 (3870–10 783)		14.6 (8.4–23.0)	
	2015	19 (13–27)		5489 (2499–9839)		12.0 (6.0–21.0)	
	2016	16 (11–22)		3455 (1643–6365)		7.3 (3.6–13.5)	
AFl/AT	2010	16 (6–30)	*P* trend <0.0001 Δ = −38%	5002 (2182–10 312)	*P* trend <0.0001 Δ = −60%	11.0 (4.4–23.7)	*P* trend <0.0001 Δ = −63%
	2011	19 (10–33)		5738 (2310–17 334)		12.8 (5.4–35.0)	
	2012	17 (10–27)		4526 (2437–8664)		10.9 (5.3–17.9)	
	2013	14 (8–26)		3651 (1676–6997)		8.2 (3.7–14.4)	
	2014	16 (9–28)		3865 (2283–10 175)		8.1 (4.8–20.4)	
	2015	10 (7–18)		2359 (935–5690)		5.0 (2.4–12.2)	
	2016	9 (5–18)		1554 (790–4355)		3.2 (1.7–8.8)	
SVT	2010	15 (8–24)	*P* trend <0.0001 Δ = −40%	2153 (1147–4215)	*P* trend <0.0001 Δ = −60%	5.4 (2.8–11.1)	*P* trend <0.0001 Δ = −60%
	2011	15 (9–22)		2204 (1245–4516)		5.9 (3.4–12.3)	
	2012	14 (9–24)		2215 (1235–4960)		5.7 (3.0–11.1)	
	2013	15 (9–22)		2059 (1187–3959)		5.2 (2.8–9.2)	
	2014	14 (6–22)		1744 (658–4351)		4.2 (1.6–11.2)	
	2015	10 (4–19)		1100 (255–3208)		3.0 (0.8–7.5)	
	2016	8 (3–15)		953 (233–1976)		2.2 (0.6–4.7)	
VT	2010	47 (34–63)	*P* trend <0.0001 Δ = −36%	18 051 (11 583–27 092)	*P* trend <0.0001 Δ = −61%	38.9 (23.8–55.3)	*P* trend <0.0001 Δ = −62%
	2011	37 (27–51)		14 152 (7968–20 724)		28.3 (16.1–41.4)	
	2012	34 (25–46)		20 524 (11 943–24 932)		41.0 (23.9–49.9)	
	2013	41 (29–55)		20 085 (10 267–30 973)		41.6 (21.1–62.6)	
	2014	35 (22–44)		14 675 (7044–23 903)		29.3 (14.7–46.3)	
	2015	32 (18–49)		9687 (3519–20 334)		19.4 (7.9–41.2)	
	2016	25 (16–39)		4870 (2633–9341)		10.0 (5.4–18.7)	
PVC	2010	23 (13–31)	*P* trend <0.0001 Δ = −53%	4268 (2477–8822)	*P* trend <0.0001 Δ = −73%	9.7 (6.2–17.9)	*P* trend <0.0001 Δ = −71%
	2011	14 (10–22)		3677 (1895–6410)		8.9 (4.1–17.7)	
	2012	18 (14–24)		4266 (2034–8504)		9.3 (4.3–17.2)	
	2013	12 (6–21)		2168 (860–4773)		5.1 (2.1–12.2)	
	2014	12 (8–21)		3663 (1274–7799)		8.1 (3.1–17.3)	
	2015	14 (9–22)		2762 (865–6673)		6.0 (1.8–13.6)	
	2016	8 (5–15)		925 (384–2453)		2.2 (0.9–5.1)	
EPS	2010	2 (1–5)	*P* trend 0.001 Δ = −12%	407 (175–939)	*P* trend <0.0001 Δ = −23%	1.0 (0.4–2.2)	*P* trend 0.02 Δ = −54%
	2011	4 (2–7)		628 (246–1566)		1.5 (0.6–3.7)	
	2012	2 (1–4)		568 (243–1478)		1.1 (0.5–3.4)	
	2013	2 (1–5)		354 (153–951)		0.8 (0.4–2.1)	
	2014	2 (1–4)		332 (165–775)		0.7 (0.4–1.7)	
	2015	2 (1–4)		272 (122–754)		0.6 (0.3–1.6)	
	2016	2 (1–4)		210 (80–478)		0.5 (0.2–1.1)	

Continued

Table 3. Continued

		Fluoroscopy Time (Min)		DAP (cGy×cm^2)		Effective Dose (mSv)	
PM/ICD	2010	6 (4–10)	*P* trend ns Δ = −11%	781 (414–1783)	*P* trend 0.0029 Δ = −44%	1.8 (1.0–3.9)	*P* trend 0.0028 Δ = −43%
	2011	6 (4–9)		824 (395–1677)		1.8 (0.9–3.7)	
	2012	5 (3–8)		658 (305–1382)		1.4 (0.7–2.9)	
	2013	4 (3–7)		570 (261–1253)		1.2 (0.6–2.7)	
	2014	4 (3–8)		629 (260–1139)		1.4 (0.6–2.4)	
	2015	3 (2–6)		450 (234–1094)		1.0 (0.5–2.3)	
	2016	4 (2–6)		450 (231–1022)		1.0 (0.5–2.3)	
CRT	2010	25 (16–32)	*P* trend 0.05 Δ = −19%	6923 (3880–10 770)	*P* trend ns	16.0 (10.7–21.5)	*P* trend ns
	2011	23 (14–32)		5239 (2788–9841)		10.5 (6.0–21.2)	
	2012	17 (12–33)		4152 (2485–6636)		8.3 (5.1–14.7)	
	2013	15 (10–33)		4108 (2633–6849)		8.3 (5.3–13.7)	
	2014	15 (10–25)		3259 (1717–6367)		7.0 (3.9–12.8)	
	2015	19 (13–29)		4800 (1963–10 721)		9.6 (4.6–21.4)	
	2016	17 (10–27)		3640 (1301–7177)		7.5 (3.5–16.7)	

AF indicates atrial fibrillation; AFl, atrial flutter; AT, atrial tachycardia; CRT, cardiac resynchronization therapy devices; DAP, dose area product; EPS, electrophysiology studies; ICD, implantable cardioverter defibrillator; PM, pacemaker; PVC, premature ventricular contractions; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

fluoroscopy time delta values ranging from −44% to −69% and DAP delta values ranging from −53% to −77% (Figure 1 and Table 5).

A strong linear relationship (r=+0.71883, P<0.0001) between fluoroscopy time and radiation dose over time was observed. Statistically different correlation coefficients were observed among operators (P<0.001), likely representing different x-ray system technical settings and utilization among operators. Table 5 shows x-ray use performance over time of the 7 experienced electrophysiological operators.

Analysis according to AF ablation technique

We compared fluoroscopy exposure data with 2 different AF ablation techniques: manual radiofrequency catheter ablations guided by electroanatomic mapping systems and cryoablation procedures. The rate of manual radiofrequency catheter ablations guided by electroanatomic mapping systems and cryoablation procedures significantly varied over time (P<0.01) as cryoablation procedures progressively increased from 13% of AF ablations in 2010 up to 27% in 2016.

Overall, 1809 (75%) manual radiofrequency catheter ablations guided by electroanatomic mapping systems were performed, counting for a median fluoroscopy time of 24 (15–36) minutes, a median DAP of 7178 (3668–13 423) cGy×cm^2 and a median ED of 15.7 (79–28.6) mSv. A cryoablation procedure was performed in 496 (21%) cases, counting for a median fluoroscopy time of 22 (15–32) minutes, a median DAP of 7820 (4195–13 853) cGy×cm^2, and a median ED of 16.7 (8.8–29.4) mSv. After statistical adjustment, the difference in fluoroscopy time was not significant between techniques but significantly higher DAP (P = 0.006) and, consequently, ED (P = 0.005) values were observed in cryoablation procedures. Over 7 years of activity, both AF ablation techniques were associated with a significant reduction of fluoroscopy time (P<0.0001), DAP (P<0.0001), and ED (P<0.0001) (Figure 2).

Preprocedural CT scan

Preprocedural CT scan was performed in 44 of 245 (18%) patients in 2010, 107 of 274 (39%) patients in 2011, 122 of 290 (42%) patients in 2012, 120 of 364 (33%) patients in 2013, 65 of 339 (19%) patients in 2014, 48 of 442 (11%) patients in 2015, and 14 of 462 (3%) patients in 2016. CT scan accounted for an adjunctive ED of 4.17±2.7 mSv until 2012 and 0.41±0.04 after 2012.[16]

Redo AF ablation procedures

We evaluated the rate of AF ablation redo procedures, and we observed that 21% of patients had previously undergone ≥1 AF ablations, with an average of 1.25 procedures and a maximum of 5 procedures per patient. In patients that underwent >1 AF ablation, the radiation dose of each procedure cumulates, and the overall radiation-related risk should be considered before performing a redo procedure.

Table 4. Fluoroscopy Time, DAP and Patient's ED in AF Ablation Procedures Performed by 7 Experienced Operators

	Op 1	Op 2	Op 3	Op 4	Op 5	Op 6	Op 7	*P* Value
N	332	347	283	231	292	250	392	
Fluoroscopy time, min	38 (26–54)	24 (18–34)	25 (18–36)	18 (10–28)	19 (14–27)	17 (11–25)	19 (13–27)	<0.0001
DAP, cGy×cm^2	12 000 (6076–20 599)	8032 (4566–14 397)	7711 (4393–14 176)	4633 (1358–9710)	5313 (2786–9865)	5447 (2968–10 398)	6265 (3031–11 173)	<0.0001
ED, mSv	26 (14–43)	18 (10–30)	16 (10–30)	11 (3–21)	12 (6–21)	12 (7–22)	14 (7–24)	<0.0001

All operators performed at least 50 AF procedures per year but, for the analysis, only procedures with availability of all clinical, procedural, and fluoroscopic data were considered. AF indicates atrial fibrillation; DAP, dose area product; ED, effective dose; N, number; and Op, operator.

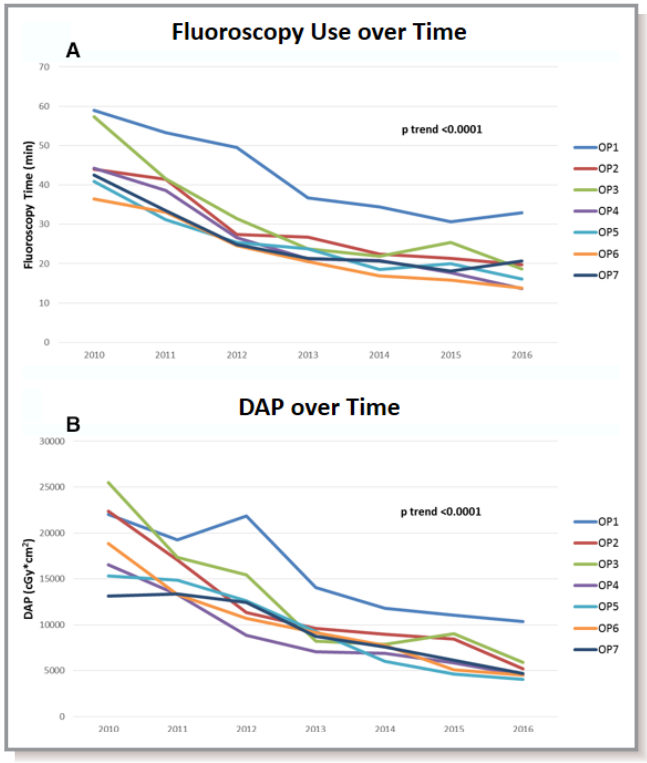

Figure 1. Fluoroscopy exposure trend per operator over time. All 7 experienced operators, over time, significantly decreased fluoroscopy time (A) and patient's dose exposure (B) during AF ablation procedures. AF indicates atrial fibrillation; DAP, dose area product; OP, operator.

Discussion

Radiofrequency catheter ablation is often the first-line therapy for several types of cardiac arrhythmias, and fluoroscopic guidance during catheter ablation remains the cornerstone in electrophysiology laboratories. Therefore, EP/DI procedures are associated with a nonnegligible radiation risk for both patients and operators. For this reason, in recent years the "ALARA" principle for cardiac interventions has been

Table 5. X-Ray Use Performance Over Time of the 7 Experienced Electrophysiology Operators

	Fluoroscopy Time (Delta, %)	DAP (Delta, %)	Correlation (*r*)	*P* Value
Op 1	−44%	−53%	+0.64227	<0.0001
Op 2	−55%	−77%	+0.66011	
Op 3	−68%	−77%	+0.70147	
Op 4	−69%	−73%	+0.7756	
Op 5	−60%	−73%	+0.65333	
Op 6	−62%	−76%	+0.75268	
Op 7	−51%	−64%	+0.69455	

DAP indicates dose area product; Op, operator.

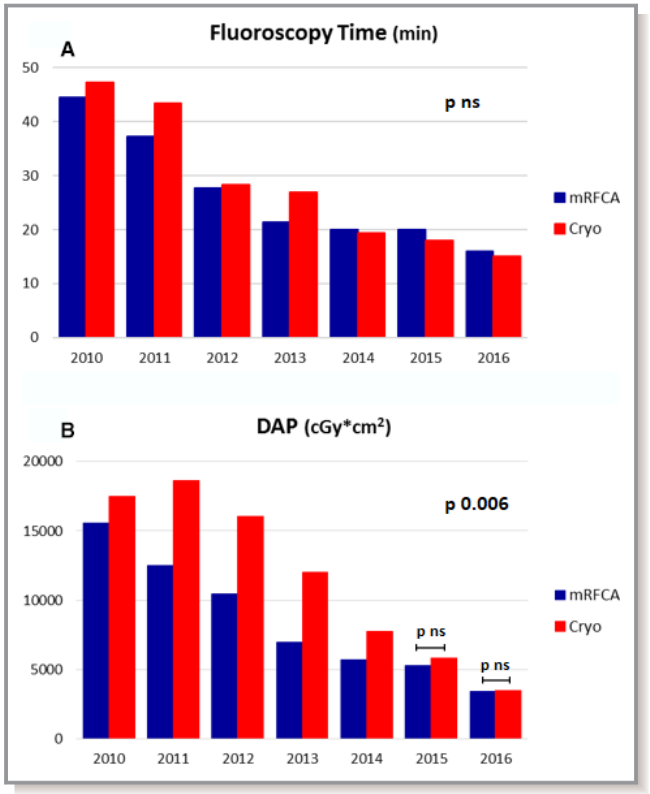

Figure 2. Comparison of fluoroscopy time and DAP between mRFCA and Cryo over time. A, Reduction of fluoroscopy time associated with mRFCA ($\Delta = -56\%$) and Cryo ($\Delta = -67\%$) procedures over time. There is no difference between the 2 techniques. B, The radiation dose reduction associated with mRFCA procedure ($\Delta = -78\%$) and Cryo ($\Delta = -80\%$) procedure over time. Considering the 7-year interval, DAP values were significantly different between the 2 techniques ($P = 0.006$). If we consider only the past 2 years, DAP values were similar between the 2 techniques (P=ns). Cryo indicates cryoablation; DAP, dose area product; mRFCA, manual radiofrequency catheter ablation.

highlighted, which means using techniques and procedures to keep x-ray exposure to a level As Low As Reasonably Achievable. Accordingly, the major cardiovascular associations have published detailed recommendations about x-ray use and suggested practical ways to reduce it.[1,12–14] Nevertheless, the majority of published studies report only fluoroscopy time (ie, an indirect measure that cannot be adequately correlated to the risk associated with x-ray exposure) and, to date, there are only a few and/or small studies reporting in detail DAP and ED.

To our knowledge, our study is the first published study performed in a large population reporting comprehensive data on fluoroscopy exposure and therefore giving an estimate of the effective risk correlated to the use of x-rays in EP and DI procedures.

Recently, Voskoboinik and colleagues[17] described a reduction in radiation dose in AF ablation over time in a large series of patients. The authors related this result to operator experience, annual case volume, technology evolution, and recent contact force–sensing catheter technology. In our experience, evaluating the trend of fluoroscopy data over 7 years, the use of x-rays was significantly reduced in most EP/DI procedures. As highlighted in previous studies, technology improvement could explain significant x-ray reduction time during more complex procedures.[18–21] We observed a significant trend in lowering use of x-ray in all types of procedures; this may not be attributed only to technology improvement.

In the workflow adaptations in order to reduce radiation exposure proposed by the European Heart Rhythm Association's Practical Guide,[1] the first recommendation regards electrophysiologists' and catheter laboratory personnel's constant awareness. This point is clearly evident in our data. Considering the analysis of x-ray use by 7 experienced operators performing AF ablation, we observed an overall significant difference in fluoroscopy use among them. The analysis of correlation between fluoroscopy time and DAP reduction over time revealed that reduction in fluoroscopy use led to a different DAP reduction among operators. These data can be attributed to several factors such as appropriate use of fluoroscopy, the operator's preference for extreme angulated left anterior oblique in contrast with "reduced" left anterior oblique or anteroposterior projection, the operator's preference for one ablation technology or another, and so on. However, over 7 years, all of the operators reduced their amount of both fluoroscopy time and DAP, showing that the use of fluoroscopy is not strictly a function of experience and that the awareness of the harm correlated with x-rays and the presence of a background in radiation safety are the cornerstones for reducing radiation exposure in interventional cardiology.[22,23]

Looking at fluoroscopy time, DAP, and ED in different procedures and for different operators, we should note that fluoroscopy time is only an indirect and incomplete measure of the radiological exposure. In fact, fluoroscopy time reduction did not always correspond to a consensual statistically significant reduction of DAP; DAP value depends on patients' body structure (eg, thoracic impedence) and appropriate use of fluoroscopy (eg, detector position, projection angle, collimation, magnification, frame-rate). Of note, the individual radiological risk is a function of patients' age and sex. Therefore, the report of fluoroscopy time should not be considered enough per se and the report of DAP and/or ED should be encouraged in all centers and studies. Furthermore, the individual lifetime excess risk of cancer incidence and mortality is estimated only thanks to the value of procedural ED.

Considering AF ablation techniques, previous papers[24] demonstrated that fluoroscopy time was longer in

Table 6. Fluoroscopy Time and DAP DRLs According to Study Population

	AF (n=2416)	AFl/AT (n=468)	SVT (n=979)	VT (n=453)	PVC (n=450)	EPS (n=1329)	PM/ICD (n=1743)	CRT (n=312)
Fluoroscopy time-DRLs	35	24	21	49	22	5	7	29
DAP-DRLs	13 628	6958	3884	23 429	6178	882	1181	8210

AF indicates atrial fibrillation; AFl, atrial flutter; AT, atrial tachycardia; CRT, cardiac resynchronization therapy devices; DAP, dose area product; DRLs, diagnostic reference levels; EPS, electrophysiology studies; ICD, implantable cardioverter defibrillator; PM, pacemaker; PVC, premature ventricular contractions; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

cryoablation than radiofrequency ablation; moreover, data of dose exposure associated with cyoablation are not available. In our long-term experience, cryoablation gradually reduced the procedural fluoroscopy time until it was comparable to radiofrequency catheter ablation. A similar trend may also be observed for dose exposure, although, over 7 years, cryoablation is still associated with higher values of DAP and ED compared to radiofrequency catheter ablation.

When performing an electrophysiological procedure, operators should always consider that it might not be the only one performed with the use of x-rays. In fact, patients may be expected to undergo ≥1 ablation procedure in their lifetime (average AF ablation procedures: 1.5 in literature,[25] 1.25 in our series), and they are often subject to other diagnostic x-ray examinations (ie, cardiac CT scan, coronary angiography, percutaneous angioplasty). In our population, a patient undergoing a rhythm control strategy with a catheter ablation varies his radiological exposure from a minimum of 3.6 mSv (one catheter ablation procedure, no preprocedural CT scan, minimum interquartile range ED value overtime) up to 100 mSv (>1 procedure, preprocedural CT scan, maximum interquartile range ED value). This results in a nonnegligible estimated excess risk of cancer malignancy induction ranging from 36 in 100 000 treated patients up to 1 in 100. Therefore, x-ray awareness and culture is particularly important in all procedures for all operators as well as patients.

Finally, we observed that our fluoroscopic exposure data were consistent with data from the European recommendations.[14] We acknowledge that there are some studies showing significantly lower x-ray exposure even in complex procedures. However, these data were obtained by designed trials with selected experienced operators and often by studies aiming at demonstrating radiation reduction exposure with different techniques. On the contrary, our data derive from the "real life" of a training center without any selection of operators and procedures and where the learning curve of electrophysiology fellows and the learning curve for the numerous continuously evolving technologies introduced should be taken into account. We acknowledge that our single-center data cannot be a reference, but we suggest that consensus groups start working on radiation exposure at a society level with the aim of proposing updated diagnostic reference levels for electrophysiological procedures. In Table 6, we propose the values of fluoroscopy time and DAP diagnostic reference levels according to our population.

Study Limitations

Our study was a retrospective analysis of procedures performed in the past 7 years; unfortunately, we had incomplete fluoroscopic data for some procedures.

Moreover, we did not report patients' body mass index, and the estimation of ED was performed with the simplified formula suggested by the European Heart Rhythm Association's Practical Guide.[1] A more accurate estimation of ED could have been done with more complex models (ie, Monte Carlo simulation) that also took into account patients' height and weight. In our experience, the simplified international formula tends to give slightly lower values than those calculated with the Monte Carlo code.[18] Consequently, our data may underestimate the real ED and the estimated lifetime attributable cancer risk.

Finally, in our population, we did not analyze a possible correlation between fluoroscopy use and procedural success. The recent paper by Voskoboinik and colleagues[17] concluded that fluoroscopy time was the only statistically significant multivariate predictor of AF recurrence; however, numerous works have shown that a reduced fluoroscopic approach does not affect procedural success.[18–21]

We should also acknowledge that we included data from operators with significantly different experience and from many procedures that also involved trainees. However, we think that it could be considered a positive feature of our study because it gives a picture of the real electrophysiological life.

Conclusions

Electrophysiological procedures involve a nonnegligible use of x-rays. Awareness of the associated risks is fundamental, and together with technological improvement, it can successfully reduce and optimize the use of fluoroscopy. Diagnostic reference levels are important for every electrophysiology laboratory to compare itself with the present standard. Currently, fluoroscopic reference values are derived from the procedures performed in previous decades. In the past few years, several papers have shown that growing operator

x-ray awareness and rapid technological advances have led to a progressive reduction in fluoroscopy use in the electrophysiology laboratories. In this context, we suggest that consensus groups start working at a society level with the aim of proposing updated diagnostic reference levels.

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Dr Dello Russo received consulting fees/honoraria from Biosense Webster. Dr Fassini received consulting fees/honoraria from Medtronic and Abbott. Dr Moltrasio and Dr Tundo received consulting fees/honoraria from Medtronic. Dr Di Biase is a consultant for Biosense Webster, Boston Scientific, Stereotaxis, and Abbott, and has received speaking honoraria from Medtronic, Atricure, EPiEP, and Biotronik. Dr Natale is a consultant for Biosense Webster, Abbott, and Janssen, and has received speaking honoraria from Boston Scientific, Biosense Webster, Abbott, Biotronik, and Medtronic. Prof Tondo has received consulting fees/honoraria from Abbott, Medtronic, Boston Scientific, and Biosense Webster, and serves as member of EU Medtronic Advisory Board and Boston Scientific Advisory Board. The other authors declare no relationships with industry.

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SUPPLEMENTAL MATERIAL

Table S1. Review of available data regarding fluoroscopy exposure.

TYPE OF PROCEDURE	REFERENCE	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)*	DAP ($cGycm^2$)*	EFFECTIVE DOSE (mSv)*
AF	Ector J et al.[1]	Observational	85	83 ± 26	11960 (1390-44630)	25.3 ± 13.8
	Smith IR et al.[2]	Retrospective	202	43.3 (28.5-58.8)	5330 (3440-7300)	7.4 (4.8-10.2)
	Rogers DP et al.[3]	Observational	Pre DRM 79 Post DRM 263	- 	6330 ± 5010 3280 ± 3170	- 2.83
	Heidbuchel H et al.[4]	**EHRA practical guide**	**-**	**-**	**-**	**16.6 (6.6-59.6)**
	Pontone G et al.[5]	Retrospective	200	-	-	32.8 ± 23.5
	Jourda F et al.[6]	Observational	RF 75 CB 75	21.5 ± 8.5 25.3 ± 9.9	4748 ± 2411 7734 ± 5361	-
	Squara F et al.[7]	Observational	RF 198 CB 178	19.3 ± 8.2 17.6 ± 11	4273 ± 2934 4853 ± 5069	-
	Schneider R et al.[8]	Observational	Pre DRM 101 Post DRM 105	29.9 ± 11.3 13.3 ± 8.3	8690 ± 5727 837 ± 647	-
	Lee G et al.[9]	Retrospective	Pre DRM 1005 Post DRM 510	41 (28.8) 9.5 (9.8)	357.10 (452.7) 104.35 (105.0)	-
	Straube F et al.[10]	Observational	RF 180 CB 193	16.0 (13.0–23.0) 16.0 (11.0–28.0)	2663 (1646–3958) 2067 (1426–2593)	-
	Wynn GJ et al.[11]	Multicenter randomized controlled	124	22.6 ± 12.7	3065 ± 4853	-
	Kleemann T et al.[12]	Observational	Pre DRM 6617 Post DRM 526	26 (17–41) 23 (13–49)	3400 (1800–6400) 800 (300–3700)	-
	Blockhaus C et al.[13]	Observational	Pre DRM 37 Post DRM 15	16.8 ± 8.8 9.5 ± 3.1	6208 ± 3314 4342 ± 2073	-
	Lehrmann H et al.[14]	Observational	Pre DRM 2005: 52 Post DRM 2015: 52	53 (41–71) 5 (4–6)	4635 (3155–6357) 185 (117–286)	9.3 (6.4–13.4) 0.4 (0.3–0.6)
	Lee JH et al.[15]	Retrospective	Pre DRM 57 Post DRM 76	24.4 (17.5–34.9) 15.1 (10.7–20.1)	599.9 (371.4–1337.5) 392.0 (289.7–591.4)	1.1 (0.7–2.5) 0.7 (0.6–1.1)
	Attanasio P et al.[16]	Observational	Pre DRM 75 Post DRM 75	14.22 ± 4.47 13.62 ± 7.11	630.28 ± 550.96 226.44 ± 277.44	-
	Rubesch-Kütemeyer V et al.[17]	Retrospective	Pre DRM CB 50 Post DRM CB 50	18±6 12±5	4935±2094 1555±1219	9.8 3.2
	Reissmann B et al.[18]	Retrospective	Pre DRM CB 60 Post DRM CB 60	14 (11–19) 10 (8–12)	2168 (1355–3490) 389 (285–550)	-

TYPE OF PROCEDURE	REFERENCE	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)*	DAP ($cGycm^2$)*	EFFECTIVE DOSE (mSv)*
VT/PVC	Smith IR et al.[2]	Retrospective	97	17.4 (9.7-26.4)	2080 (1150-3150)	2.9 (1.6-4.4)
	Heidbuchel H et al.[4]	**EHRA practical guide**	**-**	**-**	**-**	**12.5 (3-≥45)**
SVT	Smith IR et al.[2]	Retrospective	AFl 498 AVNRT 270 AVRT 135 AT 124	16.8 (9.5-30.5) 2.1 (1.3-4.5) 23.8 (13.4-45.3) 14.9 (7.7-28)	1890 (1130-3530) 260 (170-610) 2690 (1600-5410) 1770 (900-3510)	-
	Rogers DP et al.[3]	Observational	Pre DRM 214 Post DRM 417	-	2040 ± 2690 800 ± 1030	- 1.24
	Heidbuchel H et al.[4]	**EHRA practical guide**	**-**	**-**	**-**	**4.4 (1.6-25)**
	Lehrmann H et al.[14]	Observational	AVNRT 187	8 (6–13)	158 (78–338)	0.4 (0.2–0.8)
	Casella M et al.[19]	Multicentre randomized	Pre DRM 128 Post DRM 134	14.32 (9.08-22.43) 0 (0-0.2)	2036 (54–5297) 278 (80–791)	8.87 (3.67–22.01) 0 (0–0.08)
	Giaccardi M et al.[20]	Retrospective	Pre DRM 144 Post DRM 250	19.32 ± 13.88 0.23 ± 0.1	10963.3 ± 10472.2 283.4 ± 56.8	-
	See J et al.[21]	Observational	Pre DRM AVNRT 66 Post DRM AVNRT 35	20.3 ± 10.6 6.8 ± 5.8	1361.9 ± 976.9 392.0 ± 462.5	-
CRT	Butter C et al.[22]	Observational	104	20.3 ± 16	11100 ± 10100	-
	Morris M et al.[23]	Retrospective	1316	18.7 ± 0.3	2510 ± 1300	-
	Heidbuchel H et al.[4]	**EHRA practical guide**	**-**	**-**	**-**	**22 (2.2-95)**
	Thibault B et al.[24]	Observational	MG 60 CONV 70	6.5 (4.3-10.7) 19.1 (10.2-25.3)	769 (491-2182) 2608 (1333-5345)	-
	van Dijk JD et al.[25]	Retrospective	Pre DRM 183 Post DRM 230	-	7210 ± 6000 1780 ± 1740	-
PM/ICD	Tsalafoutas IA et al.[26]	Observational	55	6.6	1104	-
	Compagnone G et al.[27]	Observational	68	7.5	2570	-
	Heidbuchel H et al.[4]	**EHRA practical guide**	**-**	**-**	**-**	**4 (1.4-17)**
	van Dijk JD et al.[25]	Retrospective	Pre DRM 408 Post DRM 364	-	1640 ± 1850 520 ± 660	-
	Attanasio P et al.[28]	Retrospective	Pre DRM 280 Post DRM 304	13 ± 15 13 ± 15	3792±5025 1372±2659	-
EPS	Pantos I et al.[29]	Retrospective	237	9 (0.1-258)	1450	3.2 (1.3-23.9)
	Smith IR et al.[2]	Retrospective	732	2.1 (1.3-3.3)	240 (150-390)	0.3 (0.2-0.5)
	Heidbuchel H et al.[4]	**EHRA practical guide**	**-**	**-**	**-**	**3.2 (1.3-23.9)**

* Values are expressed as mean ± standard deviation or median and interquartile range.

AF = atrial fibrillation; AFl = atrial flutter; AT = atrial tachycardia; AVNRT = atrio-ventricular nodal reentrant tachycardia; AVRT = atrio-ventricular reentrant tachycardia; CB = cryoballoon; CONV = conventional; CRT = cardiac resynchronization therapy; DAP = dose area product; DRM = dose reduction maneuvers; EPS = electrophysiological study; ICD = implantable cardiac defibrillator; MG = MediGuide^{TM}; PM = pacemaker; PVC = premature ventricular contractions; RF = radiofrequency; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

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