



Occupational and patient radiation doses in a modern cardiac electrophysiology laboratory

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Abstract

Purpose Technological advancements have greatly expanded the field of cardiac electrophysiology, requiring greater demands on imaging systems and potentially delivering higher radiation doses to patients and operators. With little contemporary research on occupational and patient radiation risk in the electrophysiology laboratory, the aim of this study was to analyze radiation doses, including occupational fetal doses, over approximately the last decade. We benchmarked the occupational data to our patient radiation dose data to allow for comparison and to put into perspective the associated radiation risks.

Methods Occupational radiation dosimetry analyzed included data from an 11-year period for physicians, a 7-year period for nurses, and a 9-year period for fetal doses. Patient-related dose metrics over an 8-year period were also analyzed.

Results In the physician and nursing groups, there was a nearly 70% decrease in the average occupational radiation doses over the given periods. Within the electrophysiology department, the average fetal occupational doses were very low, close to 0 μ Sv. The average reference point air kerma per patient for all electrophysiology procedures decreased from nearly 600 mGy/procedure in 2010 to just over 100 mGy/procedure in 2017.

Conclusions Patient and occupational radiation doses in our laboratories significantly decreased over the periods analyzed as a result of clinical and technical staff efforts as well as advances in imaging technology. The radiation-related risk to individuals working in our electrophysiology laboratories, including pregnant women, is very low. Data reported herein could be used by other institutions to evaluate their occupational and patient radiation safety practices.

Keywords Radiation · Radiation dose · Occupational dose · Patient dose

1 Introduction

The field of electrophysiology (EP) has evolved from an emphasis on physiologic studies to therapeutic interventions that are based on an understanding of both anatomy and physiology. These interventions include complex ablation procedures, device implantations, and lead extractions that rely

heavily on radiographic imaging, a practice that exposes patients and medical personnel to ionizing radiation. The increasing complexity of EP procedures over the last several decades has led to the use of detailed three-dimensional imaging for delineation of and access to key anatomic structures, arrhythmia mapping, and substrate ablation. This increased use of imaging guidance has the potential to increase radiation exposure to patients and operators. Early in the development of ablation procedures for atrioventricular nodal reentry and atrioventricular reentry, patient radiation exposure was often estimated using anthropomorphic phantoms, external ionization chambers, and thermoluminescent dosimeters (TLDs) [1, 2]. Since 2006, International Electrotechnical Commission (IEC) standards have required fluoroscopes to include patient radiation dose surrogates such as the reference point air kerma, providing substantially improved patient-specific radiation dose metrics [3].

High patient radiation doses and their potentially severe consequences have been well documented in patients undergoing

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fluoroscopically guided interventions (FGIs) [4, 5]. These accounts, in addition to several consensus documents from the American College of Cardiology, have prompted action over the last decade to reduce patient radiation doses during cardiac FGIs whenever practicable [6, 7]. Several subsequent reports have demonstrated reductions in patient-related radiation doses over the last few years [8, 9]. However, the risk of tissue reactions in patients and the long-term stochastic risk to medical personnel remain a concern [10].

There is little contemporary research on the occupational radiation risk to staff working in the cardiac EP laboratory. Our laboratory monitors and reviews radiation doses for both patients and medical personnel. Monthly patient radiation dose summary reports are disseminated to individual physicians to identify outliers and take corrective action where needed. We hypothesized that this emphasis on best practice combined with technological advancements has reduced annual radiation exposure for medical personnel over time, and we analyzed our data to assess the effect of these measures. The aim of this study was to determine changes over time in occupational radiation doses, including occupational fetal doses. We benchmarked these data to our patient radiation dose data to allow for comparisons at other institutions. Through these efforts, we have attempted to address the magnitude of the radiation risk currently encountered by clinicians who work in EP laboratories.

2 Methods

This study was performed at Cleveland Clinic, a quaternary care medical facility. The Cleveland Clinic's main campus EP laboratory has eight dedicated interventional fluoroscopes, four each from Philips and Siemens, ranging in age from 1 year to nearly 11 years. Two of the eight fluoroscopes are newer (< 3 years) biplane fluoroscopes (one from each vendor). A full range of cardiac EP clinical procedures are performed at the institution, ranging from routine diagnostic procedures and device implantations to complex device extractions and ablations.

This study was reviewed and determined to be a quality assessment and improvement activity by the Cleveland Clinic Institutional Review Board.

2.1 Occupational and fetal dosimetry

Occupational radiation dosimetry was analyzed for cardiac EP clinical staff at Cleveland Clinic's main campus. Dosimetry data recorded over an 11-year period (2007–2017) for physicians (attendings and trainees) in the department and recorded over a 7-year period (2011–2017) for nurses in the department were used for this analysis. At our main campus hospital, fluoroscopes in the EP laboratories are operated solely by

physicians; X-ray technologists are not involved and were therefore not included in this study.

Occupational radiation dosimetry was determined by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited vendor. The radiation dose quantity used for reporting occupational dose was the effective dose equivalent (EDE), defined by the United States Nuclear Regulatory Commission and reported in the traditional units of mrem. Although this is the radiation dose quantity used for regulatory purposes in the USA, it has been replaced in many other locations by a similar radiation dose quantity reported in System International units (Sieverts [SV]), as recommended by the International Commission on Radiation Protection (ICRP). As it is common in the USA, occupational radiation doses were determined using a single dosimeter placed at the collar level, outside of any protective apparel. The dosimetry vendor applied a single dosimeter Webster correction to the dosimeter readings to account for lead-equivalent apparel [5, 11–14]. In January 2014, all occupational dosimetry switched from X-ray film to TLDs. Although both methods are accredited means of occupational dosimetry, TLDs may be more sensitive, especially at low radiation doses; this may account for some differences in the reported occupational dosimetry around those years.

Fetal dosimetry data recorded over a 9-year period (2009–2017) for declared pregnant EP staff were included in this review. Because this sample size was limited, fetal dosimetry data for pregnant EP staff (all nurses) were compared with fetal dosimetry data for pregnant staff (nurses, physicians, and technologists) from all departments using X-ray across the institution over the same time period. Fetal dose estimates were obtained using a single dosimeter placed at the waist level under any lead-equivalent apparel. Conservatively, high estimates were used whenever dosimetry data were unavailable for a month during the pregnancy period, such as the first month(s) before pregnancy was declared. In the USA, there is no regulatory or legal requirement for a woman to declare her pregnancy to her employer; this differs in many other parts of the world.

2.2 Patient dosimetry

The main focus of this research was occupational dosimetry; however, patient-related dose metrics were also analyzed for an 8-year period from 2010 through 2017 to provide a benchmark for the occupational dosimetry against which other institutions could compare their data. The patient-related dose metrics included the reference point air kerma ($K_{a,r}$) as defined by the IEC, the air kerma area product (AKAP), and the fluoroscopic X-ray beam-on time. Although $K_{a,r}$ is not specifically a patient dose, it does correlate well to the patient entrance kerma ($K_{a,e}$) and the peak skin dose. The AKAP, on the other hand, is a better metric for benchmarking occupational dosimetry as it best correlates with stochastic risks. Data on AKAP were

unreliably collected from 2010 to 2017 and, when collected, the accuracy was questionable because of confusion regarding variations in the displayed units of measure. Therefore, a second smaller data subset that contained data from 2014 to 2017 was used to estimate the AKAP from the larger dataset. This subset contained procedure radiation dose information in the form of structured dose reports generated by the fluoroscopes and was used to approximate the average X-ray field sizes for each procedure type on both large and small detector systems. The average field size data were then used to calculate an estimated AKAP for the larger data set. Table 1 shows the statistical analysis of the smaller data set used to estimate the average procedure X-ray field size. Information on fluoroscopic beam time was also included, providing a crude measure of the extent of X-ray imaging needed for a given procedure even though beam time is not an adequate surrogate for patient dose [15, 16].

Table 2 shows the total number of clinical cases in each indicated category per year in the EP department. The “devices” category includes pacemaker and implantable cardioverter-defibrillator (ICD) device implantation, including lead extraction and subcutaneous (S)-ICD procedures. The “ablations” category includes atrial fibrillation (AF), supraventricular tachycardia (SVT), ventricular tachycardia, premature ventricular complex, and atrioventricular junction ablations. There were data on 11,780 ablations from 2010 to 2017. Although there was a significant difference between years in the type of ablation (chi-square test, $p = 0.023$), the differences were relatively small. AFs ranged from 53 to 59% of all ablations with a higher percentage in 2016–2017; VTs ranged from 13 to 16% of all ablations with a higher percentage in 2012–2013; SVTs ranged from 26 to 32% of all ablations with a higher percentage in 2010.

2.3 Statistical methods

Generalized linear models were constructed to assess the effect of calendar year on dose, where the dependent variable was subjects’ dose (or log transformation, as appropriate) and the independent variable was calendar year. The overall effect of year was first assessed using a significance level of 0.05. If the overall effect was statistically significant, then differences over

the study time period were reported. To approximate AKAP, mean field size was estimated as a function of procedure and detector size from a subset of machine-generated data, with $N = 600$. SAS software 9.4 (Cary, NC) was used for all analyses.

3 Results

3.1 Occupational dosimetry

Figures 1 and 2 illustrate occupational radiation dosimetry for our cardiac EP physicians and nurses. The annual EDE limit in the USA is 50 mSv (5000 mrem). The maximum recorded occupational doses were unsurprisingly seen in the physician group, with values approaching 16 mSv (1600 mrem) in 2007 and 2009. However, over the last 4 years, the maximum values from that same group were below 5 mSv, less than 10% of the regulatory limit. In the physician group, there was a statistically significant reduction in dose over time ($p < 0.001$). Specifically, there was a significant reduction from 2007 to 2009 ($p = 0.006$), from 2009 to 2011 ($p = 0.031$), and from 2011 to 2014 ($p < 0.001$), with the dose remaining nearly constant from 2014 to 2017 ($p \geq 0.435$). In the nurse group, doses were substantially lower, with average values starting at just under 1 mSv in 2011 and decreasing to approximately 0.1 mSv in 2017. Similar to doses in the physician group, doses in the nurse group were significantly reduced over time ($p < 0.001$). Specifically, there was a significant reduction between 2011 and 2013 ($p < 0.001$), followed by another significant reduction between 2013 and 2014 ($p < 0.001$); the dose remained nearly constant from 2014 to 2017 ($p \geq 0.094$). This represents a nearly 70% decrease in occupational radiation doses over the last decade in both groups.

Figure 3 illustrates fetal dosimetry data from declared pregnant women in the cardiac EP department and in all departments using X-ray within the same institution. Note that radiation dose is reported in Fig. 3 in units of μSv , not mSv. For a declared pregnant worker, the US regulatory limit for estimated fetal radiation doses is 10% of the normal occupational deep dose limit, or 5 mSv (5000 μSv) to the fetus, over the pregnancy

Table 1 Statistical analysis of data subset for X-ray field size estimation

	Mean (<i>n</i>)	Standard deviation	Pearson correlation between $K_{a,r}$ and AKAP
Ablation			
Large detector	154.5 (272)	58.0	$R = 0.903$
Small detector	69.6 (60)	18.7	$R = 0.980$
Device			
Large detector	194.1 (183)	87.1	$R = 0.944$
Small detector	97.0 (102)	19.6	$R = 0.995$

AKAP air kerma area product, $K_{a,r}$ reference point air kerma

Table 2 Number of procedures performed in each category per year

Year	All EP procedures	All ablations ^a	All devices ^b
2010	2686	1243	1345
2011	2786	1362	1283
2012	3068	1482	1347
2013	2953	1401	1293
2014	2901	1411	1188
2015	3054	1518	1269
2016	3140	1546	1293
2017	3014	1572	1213

EP electrophysiology

^a Includes atrial fibrillation, supraventricular tachycardia, ventricular tachycardia, premature ventricular complex, and atrioventricular junction ablations

^b Includes pacemaker and implantable cardioverter-defibrillator device implantation procedures

term. Across our institution, the maximum dose reported was below 350 μSv (with a number this high seen in 1 year only), and average doses were well below 30 μSv (less than 1% of the allowable 5000 μSv). Within the EP department, the average values were very close to 0 μSv for all but 1 year (2014). In 2014, there was one outlier within the EP department with a reported fetal dose of approximately 60 μSv . In this case, it is believed that the individual inadvertently switched her collar and fetal dosimeters for an unknown number of procedures, resulting in errant readings; however, this could not be confirmed, so that data point remained unchanged.

3.2 Patient dosimetry

The average reference $K_{a,r}$ for all EP procedures decreased from nearly 600 mGy/procedure in 2010 to just over

100 mGy/procedure in 2017 (Fig. 4) ($p < 0.001$). These results were even more pronounced when the data were stratified by procedure type; the average $K_{a,r}$ for ablations decreased from more than 900 mGy/procedure in 2010 to just over 100 mGy/procedure in 2017, a decrease of nearly an order of magnitude ($p < 0.001$). These same trends held true for AKAP. Figure 5 illustrates the AKAP for device and ablation procedures performed on both large and small detector fluoroscopes. There were substantial differences in AKAP between large and small detector systems, even for the same procedure type.

The average fluoroscopy time for ablations decreased from nearly 50 min/procedure in 2010 to just over 20 min/procedure in 2017 (Fig. 6) ($p < 0.001$), accounting for a substantial portion of the reduction in average $K_{a,r}$. For device implantations, the decrease was less dramatic, but the average $K_{a,r}$ for these procedures still decreased from more than 300 mGy/procedure in 2010 to just over 100 mGy/procedure in 2017 ($p < 0.001$). Interestingly, the decrease in $K_{a,r}$ for device implantations occurred despite a nearly unchanged average fluoroscopy time over the 8-year period ($p = 0.213$). Although fluoroscopy time must not be used as a surrogate for patient radiation dose, this measure does provide a good index of the extent of X-ray imaging for a given procedure. The decreased fluoroscopy time for ablation procedures is likely a result of greater use of nonionizing imaging capabilities. The unchanged fluoroscopy time for device procedures implies that dose savings are primarily due to other factors (e.g., equipment advances, protocol optimization), not reduced fluoroscopy beam times. However, to the extent that acquisitions represent a larger fraction of the total procedure dose, fluoroscopy time becomes less indicative of the extent of X-ray imaging.

Fig. 1 Cardiac electrophysiology (EP) physician occupational radiation doses. Error bars indicate 1 standard deviation above and below the mean. EDE effective dose equivalent

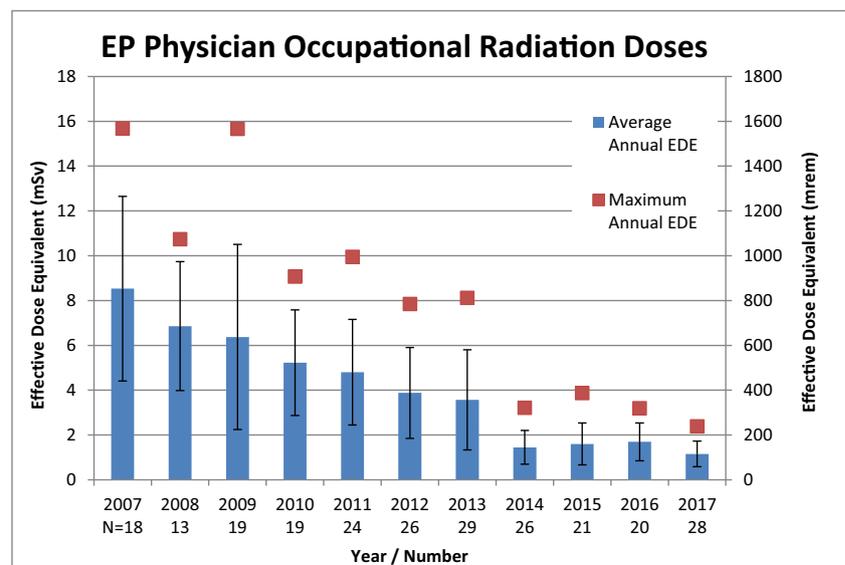
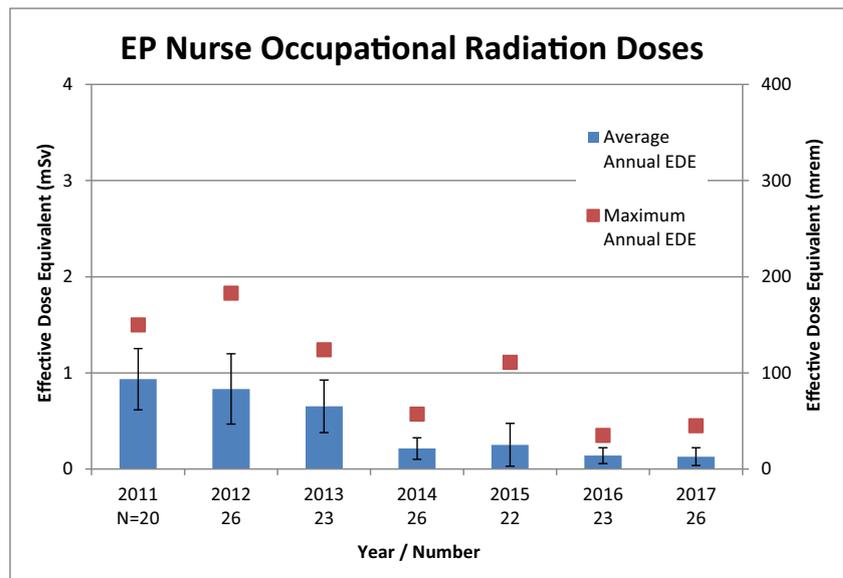


Fig. 2 Cardiac electrophysiology (EP) nurse occupational radiation doses. Error bars indicate 1 standard deviation above and below the mean. *EDE* effective dose equivalent



4 Discussion

4.1 Occupational dosimetry

In this study, we found that occupational radiation exposure for physicians and nurses in our cardiac EP laboratories has significantly decreased over the last decade and is well within the regulatory limits. However, any analysis of radiation exposure must take into account the substantial uncertainties involved in occupational dosimetry. In general, errors are skewed to result in conservative overestimates; this is for radiation protection purposes. For instance, using the single dosimeter correction factor of 0.3 multiplied by a collar dosimeter measurement may overestimate the occupational dose by as much as 500% in extreme scenarios [13, 14]. Additionally, the concept of effective dose is intended to convey risk to “standard man” from an acute radiation exposure. Its use in

estimating an individual’s cancer risk from chronic low-dose radiation exposures is inappropriate without additionally considering many other factors [17].

In the USA, the maximum permissible annual radiation dose to a worker is 50 mSv (5000 mrem); in Europe, that limit is typically 50 mSv (5000 mrem) in any individual year, with an average annualized limit of 20 mSv (2000 mrem) over a 5-year period. In this study, we found that since 2011, the mean annual radiation dose for EP physicians has been below 5 mSv and, for the last 3 years, even the maximum value has been below 5 mSv, which is 10% of the maximum permissible value in the USA. For the EP nursing staff, the mean radiation dose since 2011 has been below 1 mSv. Over the last 3 years, only 1 person in the nursing group exceeded 1 mSv, which is the radiation dose limit in the USA for a member of the public. To the best of our knowledge, these values appropriately reflect the occupational radiation doses in the department. The EP staff

Fig. 3 Average fetal doses from declared pregnant workers for all X-ray workers and for the cardiac electrophysiology (EP) department only. The maximum values correspond to the right vertical axis. *N* values represent the number of declared pregnant women across all X-ray workers and within the EP department, respectively

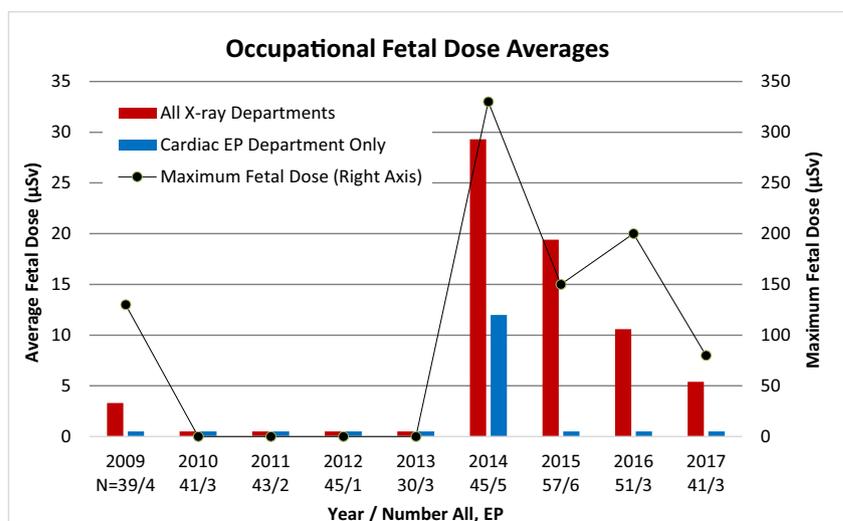
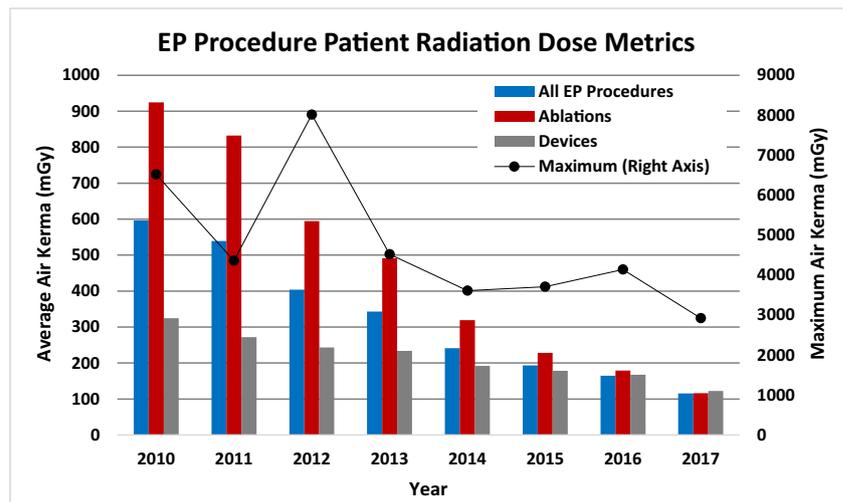


Fig. 4 Average reference point air kerma per procedure over 8 dedicated cardiac electrophysiology (EP) laboratories. Note that the maximum values correspond to the right vertical axis



members, and department as a whole, are very attentive to radiation safety and ensure proper use of occupational dosimetry during FGIs.

In 2017, a large study was published comparing mortality rates for physicians performing FGIs with those of psychiatrists over a 30-year period (1979–2008). This study found that total deaths and deaths from specific causes were not elevated in the FGI group, confirming that any radiation risk, at these levels, is uncertain at best [18]. At radiation doses higher than ~50 mSv, there is a well-known stochastic cancer risk that is approximately proportional to the radiation dose [19]. Traditionally, for radiation protection purposes, it is assumed that the linear no-threshold (LNT) model of radiation risk applies to low radiation doses. However, the risk at dose levels well below 50 mSv is, for all intents and purposes, scientifically unverifiable. What is known, however, is that if a risk exists at these levels, it is very small. Even if the LNT model were assumed to be valid at low doses, the fatal risk from

radiation doses between 1 and 5 mSv would be approximately the same as driving a vehicle 2000 miles [20].

Although occupational radiation risks have been substantially reduced over the last decade, this has been the result of concerted efforts by many professionals and must not lead to complacency. Continual efforts by clinicians and radiation experts (medical and health physicists) are required to ensure appropriate radiation safety for patients and clinical staff. Standard radiation safety practices, including the use of lead-equivalent apparel (including eyewear), tableside lead-equivalent drapes, pull-down shields, use of last-frame-hold, lowered pulse/frame rates (often to 3 pulses/s), judicious collimation, good imaging geometry, and optimization of fluoroscopy default settings, appear more than sufficient to provide a safe working environment. Additional extraneous shielding such as certain lead-equivalent operator head coverings and radiation sheets or mats provide little to no benefit, especially considering the occupational doses reported here [21].

Fig. 5 Average air kerma area product (AKAP) values for cardiac electrophysiology (EP) device and ablation procedures on both small and large detector fluoroscopes

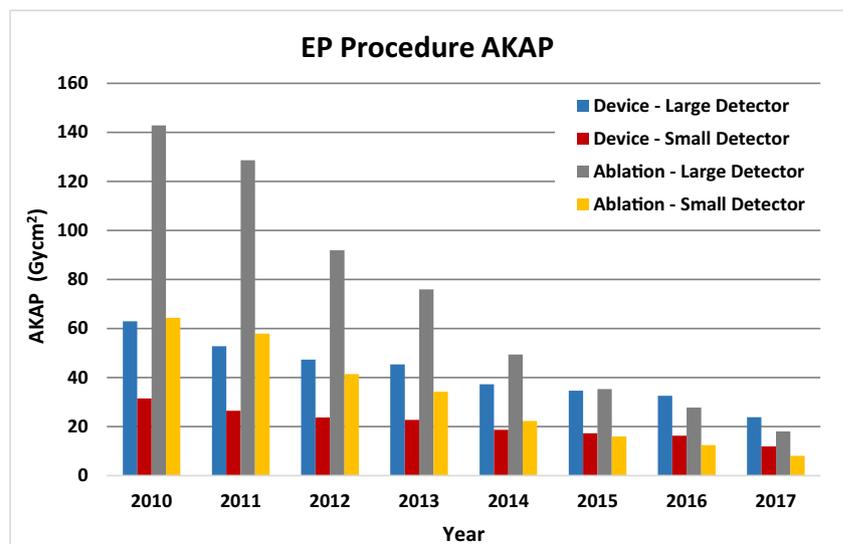
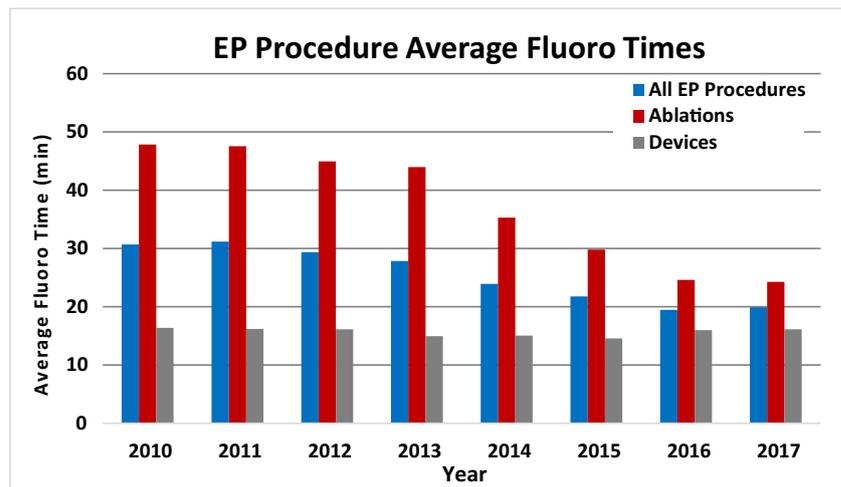


Fig. 6 Average fluoroscopy beam-on time per procedure over 8 dedicated cardiac electrophysiology (EP) laboratories



Data on fetal dosimetry are limited; however, the reported data herein indicate that pregnant women working in the cardiac EP environment need not be overly concerned about fetal exposure to occupational radiation. In the USA, declared pregnant women are limited to an exposure of 5 mSv during the pregnancy. No declared pregnant worker at our institution came close to even 10% of that limit. It is generally accepted that a minimum acute fetal dose of approximately 60 mGy (60,000 μ Gy) is required to produce an observable fetal effect [22]. This is 10 times the regulatory limit for the entire gestational period, which, for occupational workers, is more likely to be caused by chronic radiation exposure. Regardless of the risk, all pregnant women should declare their pregnancy to appropriate safety personnel as soon as practicable and receive a fetal dosimeter, which should be worn as directed to provide an appropriate estimate of the fetal radiation dose. If all standard radiation safety practices are observed, this should be more than sufficient to ensure very low fetal radiation exposure in the EP environment. Additional measures, such as wearing two aprons, provide very little to no benefit.

4.2 Patient dosimetry

The patient radiation dose metrics of $K_{a,r}$ or AKAP have also dramatically decreased over the last 8 years, a trend also reported by other recent publications [9]. The cause of these reductions can only be definitively determined through prospective scientific investigation. However, these dose reductions are due at least in part to the newer generations of fluoroscopes, which have allowed for reduced patient radiation doses [23]. Other contributing factors likely include physician training from senior physicians and medical physics staff, which began more formally around 2009; protocol optimization efforts, which have included support from clinical staff, medical physics staff, and fluoroscope vendors; and advancements in nonionizing radiation techniques such as intracardiac

catheter-based 3D mapping. However, the effect of these efforts has not been independently evaluated and can only be anecdotally associated with the observed dose reduction.

AKAP is the best available radiation quantity to correlate to occupational dosimetry because this value is proportional to the total number of photons imparted to the patient, which is the primary source of radiation for those in the procedure suite. In general, the average AKAP decreased by 60 to 75% over the time period evaluated; ablation procedures performed on large detector fluoroscopes had greater reductions, likely due to better use of collimation over time. This range in reduction was similar to the occupational dose reductions observed for physicians and nurses, providing corroboration between these two data sets.

The maximum air kerma values reported from all EP procedures (Fig. 4) are likely to have resulted in peak skin doses around the threshold level for inducing a tissue reaction. However, just beyond the threshold of approximately 3 Gy of skin dose (~ 5 Gy of reference point air kerma given numerous assumptions), the probability of a reaction is low, likely less than 1% [24]. No radiogenic tissue reactions were reported from any procedures included in this study.

5 Conclusions

Radiation doses to patients and workers in our cardiac EP laboratories have significantly decreased over the last decade, thanks to concerted efforts by clinical and technical staff as well as advancements in modern imaging technology. The radiation-related risk to individuals working in our EP laboratories, including pregnant women, is very low; staff members who follow standard radiation safety practices should have no concerns about radiation exposure. Other institutions are encouraged to compare their patient and occupational dosimetry data with ours to evaluate their clinical and radiation safety practices.

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Compliance with ethical standards

The study was approved by the institutional IRB.

Conflict of interest The authors declare that they have no conflict of interest.

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