Accurate Assessment of Patient Effective Radiation Dose and Associated Detriment Risk From Radiofrequency Catheter Ablation Procedures

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***Background*—**Radiofrequency (RF) cardiac catheter ablation procedures may require extended fluoroscopic exposure resulting in elevated radiation risk. The aim of the present study was to accurately establish RF ablation radiation risk levels and to provide means for accurate patient risk estimation from studies performed in any electrophysiology laboratory.

***Methods and Results*—**Fluoroscopy required during cardiac ablation was classified into 4 types identified by beam orientation and irradiated tissue: (1) posteroanterior exposure during catheter advancing from the groin to the heart, (2) posteroanterior heart exposure, (3) left anterior oblique heart exposure, and (4) right anterior oblique heart exposure. The duration of each exposure was monitored in 24 patients undergoing RF cardiac ablation. Dose per minute of fluoroscopy was measured at 15 organs/tissues for each projection with the use of anthropomorphic phantom and thermoluminescence dosimetry. The effective dose rate was 219, 144, 136, and 112 μGy/min for groin-to-heart posteroanterior, posteroanterior, left anterior oblique, and right anterior oblique exposure, respectively. A typical ablation procedure results in a total effective dose of 8.3 mSv per hour of fluoroscopy. The average excess of fatal cancers was estimated to be 650 and 480 per million patients undergoing RF ablation requiring 1 hour of fluoroscopy for US and UK populations, respectively. The average risk for genetic defects was determined to be 1 per million births.

***Conclusions*—**Radiation risk from RF cardiac ablation is moderate compared with other complications, but it may highly exceed radiation risk from common radiological procedures. Efforts should be made toward minimization of patient radiation risk from RF ablation procedures. **(*Circulation*. 2001;104:58-62.)**

Key Words: catheter ablation ■ radiography ■ electrophysiology ■ risk factors

In less than a decade, radiofrequency (RF) catheter ablation has evolved from a theoretic concept to first-line therapy for patients with certain rhythm disorders.[1] The procedure aims for localization and destruction of the arrhythmogenic foci or critical portions of an arrhythmia. Inserted commonly from the groin, electrode catheters are guided to the heart under fluoroscopic control in the posteroanterior (GHPA) projection, whereas fine catheter manipulations, within the heart, are commonly performed under fluoroscopic control in either posteroanterior (PA) or left or right anterior oblique (LAO or RAO, respectively) projections.[2] The procedure is highly operator dependent and usually requires prolonged fluoroscopic exposure times.[3] The cardiovascular complications, at the time of catheter ablation procedures and during short-term follow-up, have been described in the literature.[4–6] Recently, the issue of potential harmful radiation effects from catheter ablation procedures has gained increased concern, given that patients are commonly young adults, and fluoroscopy occasionally exceeds 1 hour and even results in skin injuries in some extremely rare cases.[7–10] The potential for radiation-induced cancer or genetic anomaly should not be disregarded in risk-benefit considerations, especially for individuals with many decades of expected life remaining. Therefore, patient radiation detriment risk levels should be established for the specific fluoroscopic system and technique used in every electrophysiology laboratory.[9]

The aims of the present study were to (1) accurately determine RF ablation organ dose data and patient effective dose from direct dose measurements, (2) provide data for the determination of patient radiation detriment risk from RF ablation procedures performed by use of different equipment and techniques, and (3) investigate the incidence of low-threshold deterministic effects, such as skin injuries, cataract formation, and parotiditis after RF ablation procedures.

Methods

The fluoroscopic exposures involved in a catheter ablation procedure were categorized into 4 types on the basis of beam orientation and tissue primarily irradiated: (1) GHPA exposure, involving fluoroscopy in the PA projection required for insertion and advancing the catheter from the groin to the heart, (2) PA cardiac fluoroscopic exposure, (3) 25° RAO cardiac fluoroscopic exposure, and (4) 45° LAO cardiac fluoroscopic exposure.

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Patient Study

The duration of each fluoroscopic exposure was monitored in a series of 24 consecutive patients (14 female and 10 male) undergoing catheter ablation procedures in the cardiac electrophysiology laboratory of the University Hospital of Iraklion. All patients gave informed consent. Mean patient age was 35±9 years (range 21 to 53 years). All patients suffered from symptomatic supraventricular tachycardia. Fifteen patients were diagnosed with atrioventricular nodal reentrant tachycardia, and 9 were diagnosed with Wolff-Parkinson-White syndrome. Three conventional quadripolar catheters were inserted via the left and right femoral veins and advanced to the right cardiac cavities. A special steerable catheter for mapping and ablation purposes was also advanced to the right or left cardiac cavity via the right femoral vein or artery, respectively. Mean duration of the GHPA, PA, LAO, and RAO fluoroscopic exposures was calculated.

All studies were performed by using a constant potential Philips BV300-R2 C-arm fluoroscopic unit (Philips Medical Systems) dedicated for cardiac catheterization procedures. The unit has an under-couch tube/over-couch image intensifier configuration providing the ability of last-image hold. Continuous fluoroscopy mode was used. The focus to image intensifier distance was 100 cm, and the input field size was 23 cm. Kilovoltage and tube current were selected by automatic brightness control. The measured half-value layer of the x-ray beam was 4.7 mm aluminum at 70 kV, corresponding to a total filtration of 9 mm aluminum. The x-ray tube output values at 70 cm from the tube were 1.29, 1.34, and 1.59 mGy/(min · mA) for tube voltages of 65, 67, and 70 kV, respectively.

Radiation Dose Measurements

Organ dose data were obtained separately for each of the 4 identified fluoroscopic projections involved in catheter ablation procedures from direct dose measurements on a Rando anthropomorphic phantom (Alderson Research Labs). Rando phantom has been broadly used for radiological dose measurements.[11–15] It is made by tissue equivalent material and simulates a human body trunk from the upper third of the thighs to the vertex of an individual 73.5 kg in weight and 1.73 m in height. The internal organ built into the phantom in addition to the skeleton is the lung. The lung equivalent material is sculptured to a neutral respiratory volume, and the left lung is smaller than the right to allow for the heart. The air content of the trachea, stem bronchi, and esophagus is reproduced as well. Thus, the phantom chest closely mimics a real human chest.

Lithium (thermoluminescent dosimeter [TLD]-100) and calcium fluoride TLD-200 chips (Harshaw) were used to determine the dose at 546 different measuring points in the Rando phantom. Compared with TLD-100, TLD-200 is considered preferable for dose measurement at body sites far from the primarily irradiated volume, because it presents 300 times higher sensitivity.

The phantom was appropriately loaded with TLDs to allow determination of all organ/tissue doses required for the estimation of patient effective dose according to the recommendations of the International Commission on Radiological Protection (ICRP).[16] In addition, the dose to eye lens and parotid gland was measured.

GHPA, PA, RAO, and LAO exposures were separately performed on the phantom. An experienced cardiologist positioned the x-ray tube for each projection aided by the fluoroscopic image and the internal phantom structure. The phantom was exposed for 20 minutes for each of the PA, RAO, and LAO projections, whereas GHPA fluoroscopic exposure was repeated 20 times to reduce the statistical error of dose measurements. The duration of all GHPA phantom exposures was taken equal to the average fluoroscopy time required for this projection estimated from the patient studies. A special effort was made to reproduce the table and x-ray tube movement commonly used in cardiac ablation procedures. Operating kilovoltage, tube current, and x-ray source to skin distance (SSD) for each phantom exposure were recorded. The effect of angulation on measured doses for LAO and RAO fluoroscopic exposures was evaluated by obtaining organ dose measurements for different angulations.

Organ Doses

Organ doses per minute of fluoroscopy were calculated for each exposure from the following formula:

$$d_T = \sum_i f_{Ti} \cdot d_{Ti}\,, \quad (1)$$

where d_T is the dose per minute of fluoroscopy to organ/tissue T, f_{Ti} is the fraction of total organ/tissue T mass in phantom slice i, and d_{Ti} is the average dose per minute of fluoroscopy to the volume of organ T lying within phantom slice i. The dose d_{Ti} was determined by TLDs placed within tissue T of the Rando phantom slice i. Values of f_{Ti} for gonads, thyroid, breast, lung, bone, red bone marrow, and remainder tissue were taken from Huda and Sandison.[11] Colon, stomach, bladder, liver, and esophagus f_{Ti} values were determined by using organ volume percentages per anatomic reference plane provided by Mini et al.[17] The correspondence between Rando phantom sections and reference planes has been reported by Damilakis et al.[18]

Patient Effective Dose

The effective dose per minute of fluoroscopy was calculated for each exposure by using the following formula:

$$\epsilon = \sum_T w_T \cdot d_T\,, \quad (2)$$

where w_T is the tissue weighting factors obtained from ICRP,[16] and d_T is the dose to organ/tissue T given by Equation 1.

The patient effective dose (E_{tot}) for an ablation procedure requiring t_1 fluoroscopic time for GHPA, t_2 for PA, t_3 for LAO, and t_4 for RAO projections may be determined as follows:

$$E_{tot} = \sum_{i=1}^{4} \left(\frac{O}{O_{ph}}\right)_i \left(\frac{mA}{mA_{ph}}\right)_i \left(\frac{SSD_{ph}}{SSD}\right)_i^2 \cdot t_i \cdot \epsilon_i\,, \quad (3)$$

where O and O_{ph} are the outputs at the mean operating kilovoltage used for the patient and the phantom exposure i, respectively; mA and mA_{ph} are the tube current values for the patient and the phantom exposure i, respectively; SSD and SSD_{ph} are the SSDs during phantom and patient exposure i, respectively; t_i is the duration of the fluoroscopic exposure i, and ϵ_i is the effective dose per minute of fluoroscopy for the exposure i given from Equation 2.

Detriment Risk Estimation

The radiation-induced fatal cancer risk was determined by multiplying the effective dose by appropriate risk factors. In the present study, age- and sex-related fatal cancer risk factors provided by the Biological Effects of Ionizing Radiations (BEIR) V Committee report[19] and National Radiological Protection Board (NRPB) report 260[20] were used. Derived by US[19] and UK[20] population mortality rates, Table 1 summarizes the estimates of lifetime risk for fatal cancer stratified by age at exposure and sex. The risk for radiation-induced hereditary effects was determined by multiplying mean gonadal dose with an age- and sex-averaged risk factor of 0.01 Sv^{-1}, recommended by ICRP.[16]

The minimum time of fluoroscopy required to induce skin injuries was determined by dividing the threshold dose reported[21] by the entrance skin dose rate obtained for LAO exposure, which was the maximum observed. The fluoroscopic time required to induce cataract and parotiditis was determined by dividing the corespondent threshold dose by the mean organ dose per fluoroscopic minute resulting from a typical ablation procedure. The fluoroscopy time threshold (T) for induction of a deterministic effect, applicable to any other laboratory, may be derived from the corresponding threshold T_0 provided in the present study:

$$T = T_0 \left(\frac{O}{O_0}\right)\left(\frac{mA}{mA_0}\right)\left(\frac{SSD_0}{SSD}\right)^2, \quad (4)$$

where O_0, mA_0, and SSD_0 are the output of the system, the tube current, and the SSD, respectively, used in the present study, and O, mA, and SSD are the corresponding values recorded in the other laboratory.

TABLE 1. Age- and Sex-Related Fatal Cancer Risk Factors

Age at Exposure, y	Risk, $10^{-2} \cdot Sv^{-1}$ US Population* Male	US Population* Female	UK Population† Male	UK Population† Female
10–19	11.44	15.66	9.0	10.9
20–29	9.21	11.78	6.1	7.0
30–39	5.66	5.57	4.3	4.6
40–49	6.00	5.41	4.2	4.2
50–59	6.16	5.05	4.2	3.8
60–69	4.81	3.86	3.3	2.9
70–79	2.58	2.27	1.7	1.6
80+	1.10	0.90	0.8	0.7
Average	7.70	8.10	5.8	5.9

*BEIR V Committee report[19]; †NRPB report 260.[20]

Results

Patient Study

Operating parameters and duration of the fluoroscopic exposures performed on patients undergoing RF ablation are shown in Table 2. The mean total fluoroscopy obtained from the patient measurements was 41±15 (range 15 to 67) minutes. The average relative contribution of GHPA, PA, LAO, and RAO exposures to the total fluoroscopy time was 1%, 59%, 27%, and 13%, respectively. The ablation procedure was considered successful in 92% (22 of 24) of all patients studied.

Phantom Exposure Parameters

The operating parameters and the duration of GHPA, PA, LAO, and RAO fluoroscopic exposures performed on the phantom are shown in Table 2. The phantom SSD was 60, 64, 62, and 72 cm for GHPA, PA, LAO, and RAO fluoroscopic exposures, respectively.

Organ Doses and Effective Dose

The amount of absorbed radiation dose to various organs/tissues and the total patient effective dose per minute of fluoroscopy for each of the 4 projections involved in the catheter ablation procedures are shown in Table 3. Organ doses and total effective dose per minute of fluoroscopy for a typical procedure requiring 1%, 59%, 27%, and 13% of the total fluoroscopic time spent for GHPA, PA, LAO, and RAO exposures, respectively, are also shown in Table 3. The patient tissue receiving the greatest amount of radiation dose is the skin area through which x-ray beam enters patient's body, whereas the organ receiving the greatest amount of radiation from a typical ablation procedure is the lung. Significant doses are received by esophagus, bone, stomach, breast, and red bone marrow. Besides, the greatest contribution to patient effective dose is the lung dose, followed by the dose absorbed by the esophagus, red bone marrow, and stomach. The difference in effective dose per minute of fluoroscopy for LAO and RAO projections was found to be <5% if the angulation was changed by ±10°.

TABLE 2. Operating Parameters of Patient and Phantom Exposures

Fluoroscopic Exposure	Patient Exposure kV	Patient Exposure mA	Patient Exposure Min	Phantom Exposure kV	Phantom Exposure mA	Phantom Exposure Min
GHPA	71±4	2.4±0.4	0.5±0.4	70	2.4	0.5*
PA	67±3	2.2±0.2	24±8	67	2.3	20
LAO	70±5	2.5±0.5	11±5	70	2.6	20
RAO	66±5	2.0±0.4	6±3	65	2.1	20

Patient values are mean±SD.
*Repeated 20 times.

TABLE 3. Organ and Effective Dose Rate for Exposures Involved in RF Catheter Ablation

Organ/Tissue	Organ Dose per Fluoroscopic Minute, μSv/min GHPA	PA	LAO	RAO	Typical Procedure*
Gonads	81	1	1	1	2
RBM	369	132	96	102	121
Colon	270	14	17	14	17
Lung	130	612	538	450	566
Stomach	432	94	141	117	113
Bladder	93	1	1	1	2
Breast	30	130	40	74	97
Liver	445	67	99	81	81
Esophagus	334	454	532	302	454
Thyroid	4	19	21	16	19
Skin (total)	52	47	25	28	39
Bone	875	330	240	256	302
Remainder	129	84	79	71	81
Eye lens	1	2	2	1	2
Parotid gland	2	3	4	3	3
Skin (beam entrance)	6181	4550	4825	2710	...
All tissues	216	144	136	112	138

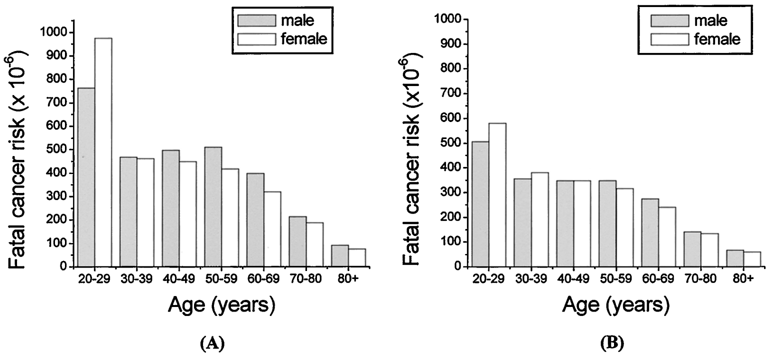
RBM indicates red bone marrow.
*RF ablation procedure requiring 1%, 59%, 27%, and 13% of total fluoroscopy for GHPA, PA, LAO, and RAO projections, respectively.

Radiation Risk

In a patient, the age- and sex-averaged fatal cancer risk from an RF ablation procedure requiring 60 minutes of fluoroscopy is 0.065% for the US population and 0.048% for the UK population; the genetic defect risk is 0.00012%. The dependence of radiation-induced fatal cancer risk on patient age and sex is shown in the Figure. In general, compared with older patients, young patients are associated with significantly higher risk. Compared with male patients of the same age, young female patients are subjected to increased risk, whereas the risk for older female patients is lower than the correspondent risk for male patients. The minimum fluoroscopic time required for the induction of various deterministic effects is shown in Table 4.

Discussion

The present study provides accurate risk levels for radiation-induced effects resulting from RF catheter ablation procedures. Data are also provided for the estimation of detriment risk for patients undergoing RF cardiac catheter ablation



Radiation-induced cancer risk dependence on age and sex of patients undergoing RF cardiac catheter ablation. Risk estimations for US population (A) and UK population (B).

procedures in other electrophysiology laboratories using different equipment and techniques.

Direct Versus Indirect Estimation of Effective Dose

Several methods have been developed for the indirect estimation of patient effective dose and risk resulting from medical exposures. With the use of such a method, organ/tissue doses and effective dose are determined by using tabular data, given the beam energy and entrance skin exposure or air kerma. Alternatively, direct organ dose measurements can be obtained within anthropomorphic phantoms. Such an approach enables direct measurement of the dose distribution within the phantom and allows reliable estimates of mean dose for any individual organ.[11] All studies found in literature reporting risk levels from ablation procedures[2,3,7,10] have involved indirect organ dose estimation from measurements of entrance skin dose or exposure. In the present study, the effective dose was determined from the organ doses measured directly by TLDs appropriately placed in a Rando phantom. An ablation procedure requiring 1%, 59%, 27%, and 13% of the total fluoroscopy time for GHPA, PA, LAO, and RAO exposures, respectively, was found to result in a patient effective dose of 8.3 mGy per hour of fluoroscopy.

TABLE 4. Fluoroscopic Time Thresholds for Induction of Deterministic Effects

	Threshold Dose, Gy	Required Fluoroscopic Time, h
Skin injuries		
Early transient erythema	2	6.7
Temporary epilation	3	10
Main erythema	6	20
Permanent epilation	7	23.3
Dry desquamation	10	33.3
Telangiectasis	12	40
Moist desquamation	15	50
Dermal necrosis	18	60
Other deterministic effects		
Cataract (not vision impairing)	1	>1000
Cataract (vision impairing)	5	>1000
Parotiditis	2	>1000

Patient Radiation Risks

For the US population, the age- and sex-averaged patient fatal cancer risk from an RF ablation procedure requiring 60 minutes of fluoroscopy was found to be 650×10^{-6}; the genetic defect risk was found to be 1×10^{-6}. In the United States, the spontaneous cancer risk is ≈20%,[19] and the incidence of serious birth defects is 6%.[22] Thus, in 1 million patients undergoing typical RF ablation procedures requiring 60 minutes of fluoroscopy, 650 extra fatal malignancies are expected in addition to the naturally occurring 200 000. Similarly, in 1 million deliveries with 1 of the parents having undergone an RF ablation procedure, 1 extra anomalous baby is expected in addition to the naturally occurring 60 000.

The minimum fluoroscopic time required for induction of the lower threshold deterministic effect, namely, transient skin erythema, was 6.7 hours. Cataract formation and parotiditis cannot be observed as a result of RF cardiac catheter ablation procedures, because both effects require huge fluoroscopic times never occurring in clinical practice. Procedures requiring <6.7 hours of total fluoroscopy are not likely to induce deterministic effects in our laboratory. This threshold is high enough, inasmuch as a modern fluoroscopic system was used in the present study, which produces a heavily filtrated beam and an entrance exposure rate of <0.005 Gy/min at 70 kVp and 70 cm from the source.

Comparison With Other Studies

The mean total fluoroscopic time required during catheter ablation procedures found in the present study (41±15 minutes) is similar to that reported by Lindsay et al[10] (50±31 minutes), Calkins et al[2] (47±40 minutes), and Rosenthal et al[3] (53±50 minutes). The considerable difference between the mean fluoroscopic time reported in the above studies and that reported by Kovoor et al[7] (94±44 minutes) may be attributed to the small number of patients studied and the use of a system not providing last-image hold. However, the large standard deviations observed in the present as well as in all previous studies demonstrate the significant variation in the total fluoroscopic exposure received by patients undergoing catheter ablation procedures.

The age- and sex-averaged radiation risks for fatal cancer and hereditary effects per hour of fluoroscopy found in the present study are presented in Table 5, together with the correspondent risks found in previous studies. Fatal cancer risk found in the present study is lower than the correspondent values reported by Calkins et al,[2] Lindsay et al,[10] and Rosenthal et al[3] but 2-fold the risk reported by Kovoor et al.[7]

TABLE 5. Age- and Sex-Averaged Risks for Fatal Cancer and Genetic Defects Resulting From RF Catheter Ablation Requiring 60-min Fluoroscopy

	Fatal Malignancy Risk, $\times 10^{-6}$	Genetic Defect Risk, $\times 10^{-6}$
Present study	650*	1
	480†	1
Calkins et al[2] (1991)	1000	20
Lindsay et al[10] (1992)	1500	12
Rosenthal et al[3] (1998)	2300	NR
Kovoor et al[7] (1998)	300	<1

NR indicates not reported.

*US population; †UK population.

Also, the genetic risk found in the present study is much lower than that obtained by Calkins et al and Lindsay et al, whereas it is similar to that reported by Kovoor et al. Inconsistencies may be attributed to the (1) increased number of organs for which dose was estimated in the present study, (2) use of modern equipment, and (3) considerable variation of the irradiated tissue volume during each fluoroscopic projection taken into account in the present study.

Data presented allow the accurate estimation of patient risk from procedures performed in any electrophysiology laboratory with different relative contribution of GHPA, PA, LAO, and RAO exposures to the total fluoroscopic time. Moreover, presented data may be used to estimate radiation risk from other cardiac catheterization procedures involving fluoroscopic projections similar to those in the present study.

Limitations of the Study

Inaccuracies in patient effective dose and associated risk determination fall into 3 categories. First, there were uncertainties related to the use of TLDs. Dosimeters were calibrated by using a radiation spectrum similar to that used during measurements, and the individual sensitivity of each TLD was used. Thus, the overall uncertainty of TLD measurements was estimated to be <10%. Second, there were inaccuracies due to the absence of direct dose measurements during RF ablation procedures performed in patients. Thus, organ doses of a patient undergoing RF ablation may differ from those measured in the phantom because of the different body dimensions. The resultant inaccuracy in effective dose and risk determination is expected to be higher in overweight patients. Third, the fluoroscopic exposures during a patient study may be performed with angulations that are somewhat different from the corresponding phantom exposures. The resultant uncertainty in risk estimations was evaluated to be <5%.

Reduction of Patient Exposure

Even if radiation risks from an average RF ablation procedure appear to be acceptable relative to the risks associated with other therapeutic approaches,[4–6] these risks are significant compared with reported risks from common radiological procedures. Therefore, efforts should be made to limit radiation exposure. The fundamental approach to moderate patient radiation exposure is to reduce the time that the beam is on. The radiation field size should be minimized to include only the anatomic region of interest. The SSD should be maintained at the maximum permissible. The equipment used should be in concordance with performance standards recommended by the US Food and Drug Administration, Center of Devices and Radiological Health.[9] Fluoroscopic systems providing a pulsed-fluoroscopy mode are preferable because of the potential for delivering a lower dose to the patient. Periodic inspection and quality control tests of the x-ray unit and image intensifier of the fluoroscopic equipment should be conducted by a medical physicist. It is noted that apart from reducing the patient dose, all the above precautions also reduce the dose to the physicians and nursing personnel involved in the study.

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