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Radiation Dose and Cancer Risk of Cardiac Electrophysiology Procedures

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ABSTRACT

Background & Objectives: This study aimed to investigate the effective dose and organ dose of radiation exposure in patients undergoing cardiac electrophysiology (EP) procedures and to estimate the risk of cancer by measuring the effective dose in staff members.

Materials and Methods: We calculated the dose by using the value of the dose-area product (DAP) to check the exposure dose in patients and staff members during EP procedures. The dose and cancer risk in staff members were estimated after the procedure by reading the optically stimulated luminescent dosimeter (OSL) attached to the radiation protection equipment.

Results: The study duration was 3 months. The total number of procedures was 89 cases (electrophysiology study [EPS] and catheter ablation: 62 cases [including 21 atrial fibrillation ablation], and pacemaker implantations: 27 cases). The mean effective dose in the primary operator over 3 months was 1.6 mSv, with a 1-year conversion of 6.4 mSv. The lifetime attributable risk of cancer (LAR) for a male primary operator with an annual exposure dose of 6.4 mSv who worked from age 18 to 65, assuming continuous exposure, for all cancers would be an incidence of 1,958 per 100,000 people. In addition, the calculated mortality rate would be 1 in 92, or 1.08%.

Conclusion: EP procedures are associated with occupational radiation exposure and an increased lifetime attributable risk of cancer. Efforts should be made to minimize the radiation exposure of patients and medical staff members.

Key Words: electrophysiology, radiation, cancer

Introduction

Electrophysiology study (EPS) and radiofrequency catheter ablation (RFCA) are widely used for the diagnosis and treatment of cardiac arrhythmias. EPS and RFCA are very complicated procedures, requiring extended periods of time and advanced technologies that vary according to the disease of the patients. Fluoroscopy is used during EPS and RFCA to guide the catheter through the vessels while viewing the fluoroscopy monitor to reach the desired area to examine and monitor the procedure. However, fluoroscopy exposes patients and staff members to radiation, and this can result in possible skin damage, cancer, and

Table 1. Mean DAP and effective dose in each procedure

Procedure	No.	Patient Weight, kg	Fluoroscopy Time, min	DAP (Gy-cm^2)	Deff (mGy)
Total	89	63 (38-88)	17.9 (0.1-68.4)	112.0 (0.3-519.6)	35.9 (0.1-166.5)
AFIB	21	68 (47-83)	38.0 (14.2-68.4)	262.5 (92.3-519.6)	84.1 (29.6-166.5)
AFL/AT	6	56 (46-66)	13.4 (8.3-13.4)	52.1 (47.9-56.2)	16.6 (15.3-18.0)
AVNRT	23	55 (45-64)	12.5 (7.1-27.4)	64.4 (15.8-203.8)	20.7 (5.1-65.3)
AVRT	9	63 (38-88)	12.8 (5.0-44.2)	60.1 (17.2-198.8)	19.8 (6.0-64.1)
PMK/ICD	27	71 (44-85)	6.3 (0.1-28.4)	31.2 (0.3-92.7)	10.0 (0.1-29.7)
VT	3	68 (64-72)	10.1 (6.0-15.4)	50.9 (24.1-81.4)	16.3 (7.7-26.1)

AFIB, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; AVNRT, atrioventricular nodal reentrant tachycardia; AVRT, atrioventricular reentrant tachycardia; CBT, concealed bypass tracts; DAP, dose area product; Deff, Effective dose; EPS, electrophysiology study; ICD, implantable cardioverter defibrillator; PMK, pacemaker; VT, ventricular tachycardia.

genetic effects.[1-3]

An existing study on radiation exposure during RFCA showed that the mean equivalent doses to the cardiologist's left hand and forehead were 0.24 mSv and 0.05 mSv, respectively, per RFCA procedure, which was more than twice the mean dose for other cardiology procedures.[4] Another study reported that cardiac electrophysiologists have high radiation exposure, with a median of 4.3 mSv per year (range 3.5-6.1 mSv).[5] In other studies of RFCA, when the patients had an effective dose of 8.3 mSv for one hour of fluoroscopy, they had a cancer risk of 480-650 per million patients.[6] Therefore, radiation exposure during electrophysiology (EP) procedures is not insignificant for both patients and staff.

According to the European Committee on Radiation Risk, when adults are exposed to a 10 mSv dose, 1 out of every 1,000 can be at risk for a possible solid tumor or leukemia in their lifetime.[7] Another report showed that if fluoroscopy exposure lasts for more than 1 hour during an EP procedure, the dosage will exceed the threshold and result in skin damage.[8] However, most cardiologists who perform procedures are not familiar with radiation physics or methods to protect against it, or did not received proper education about the risks of radiation, so individual cardiologists are subjected to different levels of exposure.[9]

Although many existing studies on radiation exposure in EP procedures have focused on effective doses in patients,[2,3,6,10] and some have examined the radiation dose in both patients and staff members,[2,11,12] few have included cancer risk in their analysis. Therefore, this study aimed to determine the effective dose and organ dose from radiation exposure during EP procedures in patients, as well as to measure the risk of cancer from the effective dose to staff members.

Materials and Methods

Patients

This study included 89 consecutive patients who received EP procedures and cardiac implantable electronic device (CIED) procedures from October 2011 to February 2012. All patients gave informed consent. Three staff members (one cardiac electrophysiologist, one radiologic technologist, and one nurse) were included for the measurement of radiation exposure.

Radiation Dose Measurement

Procedures were performed using Philips Allura Xper FD20 fluoroscopy system (Philips Medical Systems, Eindhoven, The Netherlands). The procedure was performed with fluoroscopy set to "normal" and cinematic acquisition imaging frame rates set at 15 frames/sec in cardiac mode.

The tube voltage, tube current, and radiation exposure time parameters were set at the time of installment with automatic exposure control (AEC). Tube voltage, which was between 70-120 kV, was applied according to the type and size of the

Table 2. Organ dose of the patients in the total EP procedures

Organ	Organ dose in the procedures		
	Mean (mGy)	Minimum (mGy)	Maximum (mGy)
Lung	66.22	0.20	306.94
Heart	193.47	1.00	896.53
Breast	143.46	0.40	664.76
Liver	37.29	0.10	172.77
Stomach	72.90	0.20	337.83
Spleen	35.65	0.10	165.19
Pancreas	59.92	0.20	277.66
Thymus	239.48	0.70	1,109.80

EP, electrophysiology.

patient. A basic 1.5 mm Al and filtration of 0.2 mm Cu was installed and a 0.1 mm Cu + 1.0 mm Al was applied for the Selective Fluoro Prefilter.

Calculation of the Effective Dose and Organ Dose in Patients

The dose of radiation exposure to patients during the EP procedure was measured by a dose area product (DAP) meter (Diameter PTW, Freiburg, Germany), which was attached to the collimator on the tube housing. The DAP value was used to calculate the effective dose and organ dose with the PCXMC Monte Carlo simulation program (version 1.5). The tube voltage of the X-ray, tube current, and exposure time parameters were performed by the AEC without a manual control. The tube voltage of the AEC was flexible depending upon the size of the patients and direction of the recording, ranging between 70-120 kV.

Radiation Exposure and Cancer Risk in Staff

In order to measure the radiation exposure to staff members, an optically stimulated luminescent dosimeter (OSL) (Inlight/DSL NanoDot Dosimeters, Landauer, Glenwood, IL. USA) was attached to the protective equipment. The potential measurement of the dose limit by the OSL was 100 ∂ Sv, the range of the energy was 5 keV-20 MeV, and the accuracy was ± 5% of the standard deviation. The OSL was attached at several locations: inside and outside of the gonad area, on the chest area of the apron, on the lead goggles and thyroid protector of the operator, and also inside and outside of the nurse's and radiological technologist's apron. After staff members had worn the OSL for 3 months, the data collected from the OSL was sent to a specialist who determined the radiation dose exposure at each site.

The effective dose of the staff members followed the Niklason calculation,[13] which is calculated as Deff = 0.02 (Hos-Hu) + Hu (Hos is the dose outside of the lead apron and Hu is the dose inside the lead apron). The lifetime attributable risk (LAR) of cancer for the staff member was calculated based on the BEIR VII study.[14] That study showed the occurrence of cancer per every 100,000 people when they were exposed to 10 mGy annually between the ages of 18 and 65; that data was directly applied to the calculation of cancer risk to staff members. For example, when the annual radiation exposure to staff members was 5 mSv, the LAR was 5/10×3,059/100,000. This study measured the cancer risk under the assumption that the staff members were continuously exposed to radiation from the age of 18 to 65.

Results

Radiation Dose in the Patients

The average fluoroscopic duration was 20.8 minutes during the procedure, the maximum was 68.4 minutes, and the total fluoroscopic time was 1,040.1 minutes. The DAP value was an

Table 3. Effective dose and protector attenuation rate per procedure calculated from the OSL measurements

Primary operator	Effective dose (μSv)	Attenuation rate (%)
Chest over apron	8,960	83.8
Chest under apron	1,450	
Eyes over goggle	3,200	50.4
Eyes under goggle	1,590	
Thyroid over protector	4,020	77.9
Thyroid under protector	890	
Gonadal over apron	6,930	77.6
Gonadal under apron	1,550	

OSL, optically stimulated luminescent dosimeter.

average of 112.0 Gy· cm^2, and the maximum value was 519.6 Gy· cm^2. Calculating the effective dose with the DAP value using the PCXMC program resulted in an average of 35.9 mGy with a maximum value of 166.5 mGy.

The average fluoroscopic time, DAP value, and effective dose according to each EP procedure are shown in Table 1. The fluoroscopic duration was the longest during AF ablation at 30.8 minutes, and the highest average effective dose in patients measured was 84.1 mGy. The organ dose converted with the DAP value for the entire EP procedure in patients was highest in the thymus, with an average of 239.48 mGy, followed by the heart at 193.47 mGy, and breasts at 143.46 mGy (Table 2).

Effective Dose and Cancer Risk to Staff Members

The effective dose in staff members was calculated by reading the OSL, which was worn for three months during the EP procedures. The effective dose in the primary operator who was closest to the patients for three months was 1.6 mSv, which equates to an annual radiation exposure dose of 6.4 mSv. The effective dose in the radiologic technologist was 0.98 mSv, and in the nurse it was 0.75 mSv. The dose outside the apron for the gonadal gland was 6,930 μSv, the dose in the area of the eyes was 3,200 μSv, and the thyroid was 4,020 μSv. These measurements suggest that the outside of the apron in the gonadal gland area was more exposed than the facial area. The attenuation rate, which compared the readings inside and outside of the protective gear, was calculated at 83.8% for the apron of 0.5 mm thickness, 77.0% for the 0.5 mm thyroid protector, and 50.4% for goggles with 0.07 mm lead thickness.

The cancer risk for male primary operators who are exposed to 6.4 mSv of radiation annually from the age of 18 to 65 is 1,958 per 100,000; in other words, 1 in every 51 operators would be at risk for cancer. For operators consistently exposed to 6.4 mSv per year, the mortality rate is 1 in every 92 operators (Table 3, 4).

Discussion

This study calculated the radiation dose in patients using the DAP value in order to identify the radiation exposure dose to staff members and patients during EP procedures while wearing protective gear with an OSL attached during the procedure. The amount of exposure of the patients as well as the risk of cancer was also calculated. Interventions such as EPS procedures usually use fluoroscopy. Because fluoroscopy is done by an AEC, there can be difficulty in measuring the radiation exposure dose in patients. Radiation can vary during fluoroscopy, and the exposed area of the body constantly changes; therefore, in these kinds of measurements, the dose-area product, DAP, is commonly applied. The DAP value using the DAP meter is known as an effective way to measure the amount of radiation in cardiac fluoroscopy and the radiation area during fluoroscopy.[15,16]

In the previous studies, the DAP value during EPS procedures was 11.6-251 Gy· cm^2,[4,17,18] and the effective dose in the patients

Table 4. LAR of cancer and mortality for the primary operator

Organ	Incidence		Mortality	
	LAR (per million)	Odds	LAR (per million)	Odds
Stomach	79	1:1,266	42	1:2,381
Colon	353	1:283	175	1:571
Liver	60	1:1,667	46	1:2,174
Lung	372	1:269	315	1:317
Prostate	105	1:952	205	1:488
Bladder	229	1:437	51	1:1,961
Other	513	1:195	253	1:395
Thyroid	18	1:5,556	-	-
All solid	1,727	1:58	902	1:111
Leukemia	230	1:435	186	1:538
Total	1,958	1:51	1,088	1:92

LAR, lifetime attributable risk.

was 17 mSv.[4] Kovoor stated that it was 6.34 mSv for procedures lasting 60 minutes,[3] while Lickfett reported it was between 1.48-49.75 Gy· cm^2.[2]

This study showed that the DAP value during EP procedures was an average of 112.0 Gy· cm^2 and the average effective dose in the patients was 35.9 mSv, with a maximum of 166.5 mSv. This study showed a higher average effective dose than previous studies.

During EP procedures, if patients are exposed to radiation for longer than one hour, the threshold amount of radiation that is critical for the skin will be reached, which has been reported previously.[8] During the AF ablation in this study, the exposure time was an average of 30.8 minutes, and there was a long exposure of 68 minutes, so the amount of radiation likely exceeded the limit for skin damage.

The medical staff who perform electrophysiology procedures often ignore or underestimate the danger of radiation. However, the constant exposure to radiation during a few years of work or life-long practice accumulates, and it can cause physical damage. Furthermore, cardiologists are exposed to scattered rays, which provide a fluctuating dose of radiation. In some cases, they are exposed to direct rays. Because their hands, legs, and head area are not properly protected, their accumulated dose can significantly increase. In a study by Lucia Venneri,[5] 67% of the 5,164 cardiac catheterization laboratory staff who worked with radiation in a hospital were exposed to radiation of 6 mSv or more. The study also showed that staff members who worked at cardiology centers might be exposed to the highest level of radiation. That study noted that the annual radiation exposure for interventional cardiologists averaged 3.3 mSv (2.0-19.6 mSv), and for electrophysiology cardiologists it was 4.3 mSv (3.5-6.1 mSv), equating to a fatal cancer risk of 1 in 384. The all-cause cancer risk is 1 in 192. In the BEIR study,[14] staff members exposed to 2 mSv of radiation annually from the age of 18 to 65 had cancer risks of 612/100,000 for men or 859/100,000 for women. In other words, the all-cause cancer risk for exposed staff was 1 in 136 and the mortality rate was 1 in 245. Another study found that the effective radiation dose in operators during percutaneous coronary intervention procedures was 0.17-31.2 μSv and 0.24-9.6 μSv during EP and ablation procedures.[19]

In the present study, the effective radiation dose in staff members during the EPS procedure was 1.6 mSv over three months of exposure for primary operators, with an annual exposure of 6.4 mSv. Extrapolating from this data, the all-cause cancer incidence is 1 in 51, and the mortality rate is 1 in 92. Therefore, although radiation exposure during EP procedures is not immediately harmful in primary operators, over time, the cumulative exposure can increase cancer risk. Radiation exposure generally occurs due to scattered rays, except in the instances when operators put their hands into the fluoroscopic field to operate the catheter. Fluoroscopy rays scatter in the iris of the radiation tube, via leakage, and from reflection of patients.[20] With the under tube method, most rays reflected from the patients under the table, which can directly affect the gonadal glands. In this study the under tube method was used during EP procedures, and, as a result, radiation exposure to primary operators appears higher in the gonadal glands than in the eyes or thyroid gland. The results of this study showed the same conclusion as the previous study.

Although operators wear aprons, lead shields, and goggles to protect themselves, during long-term performance of these procedures, it is impossible to avoid radiation exposure and its effects. If operators fail to use protective gear or adjust the exposure time properly, within a few years their eyes, skin, thyroid, and gonadal glands may have increased cancer risk. The attenuation rate of the protection equipment identified in this study was 83.8% for a 0.5 mm lead apron, 77.9% for a 0.5 mm lead thyroid protector, and 50.4% for 0.07 mm lead goggles. This means that current equipment does not fully protect workers from radiation exposure. The attenuation rate varied depending on the kind. The most effective methods to reduce radiation exposure during cardiac interventional procedures include education regarding long-term exposure, developing a program to decrease exposure to patients, installing proper equipment, and using appropriate protective gear. Another method for reducing exposure is in the operation of the machine. By setting a low level for the fluoroscopy mode, preventing any unnecessary screen widening, minimizing the source image distance (SID), maximizing the source object distance (SOD), using a proper filter, and selecting an image capture instead of spot image, exposure to radiation for both patients and staff could be reduced.

The study had several limitations. First, the amount of indirect radiation exposure in the patients could differ from the amount of direct radiation exposure because of the calculation of the radiation exposure using the PCXMC program with the DAP value. Second, this study calculated the risk of cancer using the BEIR VII study, but the potential cancer risk could be higher in this study. This study ruled out many factors that could influence the effective dose during the procedure, such as personnel, mechanical, and environmental factors. Because the procedures were performed with cardiac mode and a high frame rate setting, the amount of radiation exposure was higher than we expected. Recently, the fluoroscopic setting was changed to “low” and cinematic acquisition imaging frame rates changed to 3.75 frames/sec in cardiac EP mode. Therefore, we assume that the amount of radiation exposure was much reduced as compared to the study results.

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