Radiation exposure to patients’ skin during
cardiac resynchronization therapy

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Received 6 May 2009; accepted after revision 10 September 2009; online publish-ahead-of-print 20 October 2009

Aims
The purpose of the current study is to evaluate the patients’ entrance skin dose (ESD) during cardiac resynchronization therapy (CRT).

Methods and results
Entrance skin doses were assessed during 16 CRT procedures. Seven of the 16 patients were upgrade of conventional pacemaker to CRT. The patients wore jackets which had 100 radiosensitive indicators placed on the back during the procedures. After the procedure, the patients’ ESDs were calculated from the colour difference of the indicators. Eleven of the 16 patients were implanted devices with a defibrillator, and three patients those without a defibrillator. In the other two, the procedures failed. The average total fluoroscopic time (TFT), total numbers of cine frames, and the maximum ESDs were 56.7 ± 28.0 min, 674 ± 342 frames, and 1.0 ± 0.6 Gy, respectively. Of the 16 patients, six received ESDs exceeding 1 Gy; TFT, total number of cine frames, and the maximum ESD tended to decrease as the operator experience increased.

Conclusion
The patients’ ESDs during CRT procedures can exceed the thresholds for radiation skin injuries due to prolonged fluoroscopic times. Therefore, interventionalists should estimate the doses.

Keywords
Cardiac resynchronization therapy • Dosimetry • Radiation safety

Introduction
Cardiac resynchronization therapy (CRT) is a new technique for treatment of heart failure. In patients with New York Heart Association class III or IV heart failure, CRT has been shown to reduce symptoms and improve left ventricular function.1–4 In this procedure, coronary sinus implantation of a lead is time consuming,5 and the radiation exposure may exceed the thresholds of skin injuries. However, to our knowledge, the patient’s entrance skin dose (ESD) in this procedure has not been assessed in the literature. The purpose of this research is to assess patients’ ESD during CRT.

Methods

Patient population
This study focused on consecutive 16 patients (5 women and 11 men) who underwent CRT procedure with evaluation of the ESDs from January 2007 to October 2008. Clinical characteristics of the 16 patients were summarized in Table 1. Average patient age was 69.6 ± 7.9 years (range: 56.6–86.5). Patient height, weight, and body mass index were 158 ± 6 cm (range: 148–168 cm), 55.4 ± 7.6 kg (range: 46.0–69.5 kg), and 22.2 ± 2.7 kg/m² (range: 17.5–25.7 kg/m²), respectively. Seven of the 16 patients were upgrade of conventional pacemaker to CRT (single chamber: two patients, dual chamber: five patients).

Angiographic unit and cardiac resynchronization therapy procedure
AdvantX LC/LP (General Electric Medical Systems, Milwaukee, WI, USA) was used as the angiographic unit. Although it was a biplane angiographic system, it was used as a single-plane angiographic system in the current study. The period of use of the unit was 12 years. The image intensifiers of the unit were renewed in April 2004. The unit had an undercouch tube and an overcouch image intensifier with three fields of view (FOVs): 9, 6, and 4.5 in. in diameter. Nine-inch FOV was used mainly for CRT, and 6 in. FOV...
for percutaneous coronary intervention (PCI). The total filtrations were equivalent to those of 2.7 mm aluminium. Procedures were performed with pulse-mode fluoroscopy of 25 pulses per second. For cine acquisition, the frame rate was 12.5 frames per second. In both fluoroscopy and cine acquisition, the low-dose modes were used. According to the manufacturer, these dose rates were about half of those used in PCI procedures, when the same sizes of FOVs are used. One cardiologist performed all the procedures, and all leads were implanted transvenously in each patient. Insynk III 8042U (Medtronic Inc., Minneapolis, MN, USA) was used as a CRT device without a defibrillator, and Insync III Marquis 7279, Concerto C154DWK, or Concerto-AT C174AWK (Medtronic Inc.) was used as a CRT device with a defibrillator. The procedures failed. The average TFT was 56.7 min (range: 20.8–114.8 min), and the average total number of cine frames was 674 ± 342 frames (range: 189–1329 frames). The average of the maximum ESD for each patient was 1.0 ± 0.6 Gy (range: 0.3–2.5 Gy). Of the 16 patients, six received the maximum ESDs exceeding 1 Gy. The maximum ESD per TFT tended to be larger for patients with larger body mass index (Tables 1 and 2).

**Results**

Implantation data of the 16 patients were summarized in Table 2. Eleven of the 16 patients were implanted CRT devices with a defibrillator and three patients devices without a defibrillator. In the other two, the procedures failed. The average TFT was 56.7 ± 28.0 min (range: 20.8–114.8 min), and the average total number of cine frames was 674 ± 342 frames (range: 189–1329 frames). The average of the maximum ESD for each patient was 1.0 ± 0.6 Gy (range: 0.3–2.5 Gy). Of the 16 patients, six received the maximum ESDs exceeding 1 Gy. The maximum ESD per TFT tended to be larger for patients with larger body mass index (Tables 1 and 2).

Linear regression demonstrated a significant correlation between TFT and the maximum ESD 
\[ r = 0.621; \ P = 0.0109; \] the maximum ESD (Gy) = 0.189 + 0.0137 × TFT (min) \] (Figure 1). However, wide variation among individual instances was observed.

Total fluoroscopic time, total number of cine frames, and the maximum ESD tended to decrease as the operator experience increased (Figure 2). The average TFT and maximum ESD of the last six procedures were about half of those of the first five procedures.

Figure 3 shows the averaged TFTs and maximum ESDs of the successful new implantation (n = 9), successful upgrade procedures (n = 5), and failed procedures (n = 2). The two failed
procedures were upgrade cases. The averaged TFT (102.7 ± 17.1 min) and maximum ESD (1.3 ± 0.6 Gy) of the failed procedures were larger than those (TFT, 50.2 ± 22.5 min; maximum ESD, 0.9 ± 0.6 Gy) of successful procedures.

Discussion
Acute radiation doses may cause early transient erythema at 2 Gy, temporary epilation at 3 Gy, and permanent epilation at 7 Gy.\(^9,10\)

Radiation skin injuries in patients have been reported more frequently with the spread of interventional radiology (IR). The Food and Drug Administration (FDA) has listed some IR procedures for which interventionalists should be aware of the potential for serious radiation-induced skin injury.\(^11\) These procedures include radiofrequency cardiac catheter ablation, PCI, stent, and filter placement and thrombolytic and fibrinolytic procedures. In order to prevent radiation skin injuries during IR procedures, the FDA recommended to identify and record those areas of the patient’s skin that received an absorbed dose exceeding 1 Gy during IR procedures.\(^12\) The International Commission on Radiological Protection also recommended that the maximum skin dose and its location should be recorded, when the maximum cumulative skin dose is supposed to be 3 Gy or more (1 Gy or more in repeatable cases). In the current study of the 16 CRT procedures, the maximum ESDs exceeded 1 Gy in six procedures. Therefore, CRT should be added to the procedures in which the radiation exposure can induce skin injuries.

Table 2 Implantation data of the 16 patients

<table>
<thead>
<tr>
<th>Procedure no.</th>
<th>Procedure time (min)</th>
<th>TFT (min)/estimated dose* (Gy)</th>
<th>Total number of cine frames/estimated dose* (Gy)</th>
<th>Maximum ESD (Gy)</th>
<th>Defibrillator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>220</td>
<td>114.8/1.5</td>
<td>1115/0.2</td>
<td>0.8</td>
<td>Failed</td>
</tr>
<tr>
<td>2</td>
<td>180</td>
<td>35.0/0.5</td>
<td>1179/0.2</td>
<td>1.2</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>170</td>
<td>36.6/0.5</td>
<td>558/0.1</td>
<td>0.7</td>
<td>+</td>
</tr>
<tr>
<td>4</td>
<td>200</td>
<td>98.4/1.3</td>
<td>664/0.1</td>
<td>2.5</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>170</td>
<td>57.6/0.8</td>
<td>611/0.1</td>
<td>0.7</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>210</td>
<td>39.7/0.5</td>
<td>388/0.1</td>
<td>0.5</td>
<td>+</td>
</tr>
<tr>
<td>7</td>
<td>180</td>
<td>47.1/0.6</td>
<td>433/0.1</td>
<td>0.4</td>
<td>–</td>
</tr>
<tr>
<td>8</td>
<td>270</td>
<td>92.8/1.2</td>
<td>633/0.1</td>
<td>1.4</td>
<td>+</td>
</tr>
<tr>
<td>9</td>
<td>230</td>
<td>66.9/0.9</td>
<td>1174/0.2</td>
<td>1.9</td>
<td>+</td>
</tr>
<tr>
<td>10</td>
<td>270</td>
<td>90.6/1.2</td>
<td>189/0.0</td>
<td>1.7</td>
<td>Failed</td>
</tr>
<tr>
<td>11</td>
<td>110</td>
<td>31.4/0.4</td>
<td>1329/0.2</td>
<td>0.6</td>
<td>–</td>
</tr>
<tr>
<td>12</td>
<td>190</td>
<td>49.4/0.7</td>
<td>560/0.1</td>
<td>0.4</td>
<td>+</td>
</tr>
<tr>
<td>13</td>
<td>170</td>
<td>50.7/0.7</td>
<td>329/0.1</td>
<td>1.0</td>
<td>+</td>
</tr>
<tr>
<td>14</td>
<td>105</td>
<td>20.8/0.3</td>
<td>399/0.1</td>
<td>0.4</td>
<td>–</td>
</tr>
<tr>
<td>15</td>
<td>140</td>
<td>31.6/0.4</td>
<td>687/0.1</td>
<td>0.8</td>
<td>+</td>
</tr>
<tr>
<td>16</td>
<td>150</td>
<td>44.6/0.6</td>
<td>536/0.1</td>
<td>0.5</td>
<td>+</td>
</tr>
<tr>
<td>Average ± SD</td>
<td>185 ± 48</td>
<td>56.7 ± 28.0/0.8 ± 0.4</td>
<td>674 ± 342/0.1 ± 0.1</td>
<td>1.0 ± 0.6</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

TFT, total fluoroscopic time; ESD, maximum skin dose.

\(^*\)Estimated doses receiving during fluoroscopy and cine acquisition were calculated based on a dose rate of fluoroscopy (13 mGy/min) and that of cine acquisition (0.18 mGy/frame), which were evaluated at the interventional reference point on a water-equivalent phantom with a thickness of 20 cm.

Figure 1 Relationship between the TFT and maximum ESD. Regression line is represented by a solid line. The maximum ESDs and the TFT correlated (\(r = 0.621, P = 0.01019\)). The regression equation was \(D = TFT \times 0.0137 – 0.189\), where \(D\) was the maximum ESD; TFT was the total fluoroscopic time.

Radiation skin injuries in patients have been reported more frequently with the spread of interventional radiology (IR). The Food and Drug Administration (FDA) has listed some IR procedures for which interventionalists should be aware of the potential for serious radiation-induced skin injury.\(^11\) These procedures include radiofrequency cardiac catheter ablation, PCI, stent, and filter placement and thrombolytic and fibrinolytic procedures. In order to prevent radiation skin injuries during IR procedures, the FDA recommended to identify and record those areas of the patient’s skin that received an absorbed dose exceeding 1 Gy during IR procedures.\(^12\) The International Commission on Radiological Protection also recommended that the maximum skin dose and its location should be recorded, when the maximum cumulative skin dose is supposed to be 3 Gy or more (1 Gy or more in repeatable cases). In the current study of the 16 CRT procedures, the maximum ESDs exceeded 1 Gy in six procedures. Therefore, CRT should be added to the procedures in which the radiation exposure can induce skin injuries.

Summary of safety and effectiveness of a CRT-D system\(^13\) showed that increased investigator experience with the procedure decreased the TFT. According to the data, the average TFTs were ~50 min for the first three procedures, and ~35 min after the 15th procedure. Also in the current study, the average TFTs were 68.5 min for the first five procedures, and 38.1 min after the 10th procedure. However, the TFT for CRT procedures is longer than that for PCI procedures. According to the report of CRT of Duray et al.,\(^14\) the TFT of de novo implantations and upgrade procedures were 25 ± 18 min and 32 ± 22 min, respectively. On the other hand, Hwang et al.\(^15\) reported that the TFT and the maximum ESD for PCI with a single stent were 16 ± 6 min and
1.5 ± 0.6 mGy, respectively. Suzuki et al.\textsuperscript{16} reported that the TFT and the maximum ESD for PCI for one stenotic lesion were 15 ± 8 min and 1.4 ± 0.9 mGy, respectively.

When compared with the maximum ESDs during PCI in the literature, the maximum ESDs during CRT in the current study (1.0 ± 0.6 Gy) were relatively low in spite of longer fluoroscopic times. Several factors contributed to the relatively low maximum ESD. The smaller number of cine frames was related to the lower maximum ESD. According to the preliminary reference levels proposed by Neofotistou et al.,\textsuperscript{17} the levels for percutaneous transluminal coronary angioplasty (PTCA) were 16 min for fluoroscopic time and 1355 frames for cine acquisition. In the current

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**Figure 2** The effects of operator experience on the total fluoroscopic times (A), total numbers of cine frames (B), and maximum ESDs (C). These values tended to decrease as the operator experience increased.

**Figure 3** The averaged total fluoroscopic times (A) and maximum ESDs (B) of the successful new implantation, successful upgrade procedures, and failed procedures.
study for CRT procedures, the TFT were ~4 times as large as the reference level for PTCA, whereas the number of cine frames was about half of the reference level.

The sizes of FOVs and the modes of dose rates affect the maximum ESDs, too. When compared with CRT procedures, more detailed images are needed for PCI procedures, and they require a smaller FOV and higher dose rate. Selection of appropriate size of FOV and appropriate dose rate is required for CRT procedures, since the TFT of the procedure is long. In the current study, the dose rates selected for CRT procedures were about a half of those for PCI procedures, when the same sizes of FOVs were used. In general, pulsed fluoroscopy at a lower pulse rate is useful to reduce the patients’ skin dose during fluoroscopy. Also, in the current study, the dose rates selected for CRT procedures were about a half of those for PCI procedures, when the same sizes of FOVs were used. In general, pulsed fluoroscopy at a lower pulse rate is useful to reduce the patients’ skin dose during fluoroscopy.

In conclusion, the patients’ skin doses during CRT procedures can exceed the thresholds for radiation skin injuries due to prolonged fluoroscopic times. Therefore, interventionalists should estimate the patients’ skin dose and make efforts to reduce maximum ESDs in the CRT procedures.

Conflict of interest: none declared.

References


Abdominal twitching due to inadequate stitching

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A 64-year-old male with a single-chamber ICD, implanted 3 months prior (Panel A), presented with sudden onset rhythmic abdominal twitching. Physical exam was notable for diaphragmatic contractions. A chest X-ray demonstrated lead retraction into the superior vena cava-right atrial junction (Panel B, arrow). Onset of symptoms correlated to a sudden drop in ventricular sensing (Panel C). Loss of sensing and capture was also noted on the ECG (Panel D, pacing artefact denoted by arrows). Symptoms resolved immediately with pacing turned off. Fluoroscopy demonstrated right-sided diaphragmatic stimulation during ventricular pacing prior to lead revision (see the movie file available in supplementary material online), consistent with right phrenic nerve capture. Lead dislodgement was due to suboptimal anchoring of the lead to the suture sleeve.

Supplementary material
Supplementary material is available at Europace online.

Conflict of interest: none declared.