Use of a Dose-dependent Follow-up Protocol and Mechanisms to Reduce Patients and Staff Radiation Exposure in Congenital and Structural Interventions

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Background: Increasingly complex structural/congenital cardiac interventions require efforts at reducing patient/staff radiation exposure. Standard follow-up protocols are often inadequate in detecting all patients that may have sustained radiation burns.

Methods: Single-center retrospective chart review divided into four intervals. Phase 1 (07/07–06/08, 413 procedures (proc)): follow-up based on fluoroscopy time only; frame rate for digital acquisition (DA) 30 fps, and fluoroscopy (FL) 30 fps. Dose-based follow-up was used for phase 2–4. Phase 2 (07/08–08/09, 458 proc): DA: 30 fps, FL: 15 fps. Phase 3 (09/09–06/10, 350 proc): DA: 15–30 fps, FL: 15 fps, use of added radiation protection drape. Phase 4 (07/10–10/10, 89 proc): DA: 15–30 fps, FL: 15 fps, superior noise reduction filter (SNRF) with high-quality fluoro-record capabilities. Results: There was a significant reduction in the median cumulative air kerma between the four study periods (710 mGy vs. 566 mGy vs. 498 mGy vs. 241 mGy, \( P < 0.001 \)), even though the overall fluoroscopy times remained very similar (25 min vs. 26 min vs. 26 min vs. 23 min, \( P = 0.957 \)). There was a trend towards lower physician radiation exposure over the four study periods (137 mrem vs. 126 mrem vs. 108 mrem vs. 59 mrem, \( P = 0.15 \)). Fifteen patients with radiation burns were identified during the study period. When changing to a dose-based follow-up protocol (phase 1 vs. phase 2), there was a significant increase in the incidence of detected radiation burns (0.5% vs. 2%, \( P = 0.04 \)).

Conclusions: Dose-based follow-up protocols are superior in detecting radiation burns when compared to fluoroscopy time-based protocols. Frame rate reduction of fluoroscopy and cine acquisition and use of modified imaging equipment can achieve a significant reduction to patient/staff exposure.

Key words: congenital heart disease; structural heart disease; radiation exposure; radiation protection; fluoroscopy

INTRODUCTION

Radiation protection and patient/staff dose monitoring are essential quality and safety tools within the cardiac catheterization laboratory. Patients with congenital heart disease frequently undergo numerous diagnostic and therapeutic catheterization procedures, in addition to other imaging studies such as CT scans [1]. The frequency and duration of these procedures has increased notably over the last two decades as a result of advances made in transcatheter techniques and armamentarium available to the interventional cardiologist. Although the long-term effects of this exposure are not known and difficult to estimate, there is significant concern especially about long-term stochastic effects of this “friendly fire” [2], such as solid tumors and leukemia. This is especially true in children [3], as growing tissue is much more sensitive to the biological effects of radiation. Furthermore, children have much more time to survive long enough through the latent period that often occurs before malignancies develop and therefore are more likely to eventually manifest late effects of radiation exposure.
Data on the exact incidence of acute/semi-acute deterministic effects such as radiation burns is scarce, and the incidence depends to a degree on the quality of the follow-up protocol. Fluoroscopy-time-based follow-up protocols are still used in many institutions but are inadequate to provide good thresholds for follow up. Frequently, high upper limits are used, which may be insufficient to detect all incidences of radiation burns.

The Society for Cardiovascular Angiography and Interventions (SCAI) recently revised a “Radiation Safety Program” with specific recommendations for patients with congenital and structural heart disease [4]. While these guidelines clearly recommend minimizing frame rate of fluoroscopy and cine acquisition, as well as minimizing the use cine recordings, very little data exists on the exact impact on reducing radiation exposure to staff and patient. In response to renewed efforts at reducing radiation exposure, manufacturers have made progress developing equipment with superior fluoroscopy recording abilities, with very little quality degradation when compared to conventional cine acquisition.

The purpose of this study was to evaluate the incidence of radiation burns and to compare follow-up protocols based on fluoroscopy-time with those based on total radiation dose. Furthermore, this study was designed to evaluate and quantitate the dose reduction of patient and staff exposure that can be achieved, using a variety of mechanisms, such as frame rate reduction (cine and fluoro), use of additional scatter protection, as well as utilization of new equipment with superior fluoroscopy-recording capabilities to reduce the need for conventional cine acquisition.

METHODS

The study was conducted as a single-center retrospective chart review. Institutional review board (IRB) approval was obtained. Data were collected between July 2007 and October 2010 and included procedure type, physician and patient radiation exposure, and the occurrence of radiation burns. Patient radiation exposure was quantified by using the fluoroscopy time, as well as the patient dose. The X-ray dose was provided by the manufacturer as cumulative air kerma measured in milligray (mGy). The dose area product was initially not provided by the manufacturer and as such was not included in this study. Physician radiation exposure was measured as a median monthly deep dose equivalent (in mrem), as measured from the radiation badges and after applying EDE-1 and EDE-2 equations. Throughout the study period fellows were rarely performing cardiac catheterization (with exception of vascular access) and as such their exposure was not accounted for in this study.

Two different patient monitoring systems for radiation burns were compared. The original system was used until June 2008, and it was based exclusively on fluoroscopy time. Patients with a fluoroscopy time exceeding 120 min required a patient information leaflet, and a follow-up phone call. A new patient monitoring system was implemented in July 2008 consisting of three levels of follow-up, depending on cumulative air kerma. Patients received an information sheet about the radiation exposure between 2,000-5,499 mGy, as well as a follow-up phone call at 1 week and were educated on the signs and symptoms of radiation burns. Between 5,500-8,999 mGy, patients received additional follow-up phone calls at 3, and 6 weeks postprocedure. From 9,000 mGy, patients had an additional scheduled clinic visit within 6 weeks of the procedure. Patients with any documented radiation burn were referred to a burn clinic for evaluation and treatment. During phase 4, the follow-up protocol was modified slightly, to thresholds of 3,000, 6,000, and 9,000 mGy, to accommodate the fact that the lowest cumulative air kerma in a patient with a subsequent radiation burn was 3,810 mGy (which occurred prior to the study period).

In addition to trying to improve the detection of radiation burns through a modified follow-up protocol, a variety of changes were introduced into the routine setup of the catheterization laboratory, to facilitate lower patient and staff radiation exposure. Those included changes to preset standard frame rate for acquisition and fluoroscopy, as well as modifications and upgrades to the X-ray equipment (PureBrain®, Toshiba), which facilitates fluoroscopic recording at qualities comparable to image acquisition (Fig. 1a and b), using superior noise reduction filter (SNRF).

In addition, towards the end of 2009 the RADPAD® (Worldwide Innovations & Technologies, Overland Park, KS), a sterile, lead-free, bismuth-based, disposable radiation protection drape, was introduced into the laboratory to aid in the reduction of physician/staff exposure to radiation scatter. In addition to the use of the normal lead apron, the RADPAD complements the radiation protection of the operator by being placed below the inguinal puncture site, thereby reducing the amount of radiation scatter to the physician.

To allow comparisons of these changes, the study period was divided into four phases (Table I). Electrophysiological procedures were not included into the outcome analysis.

Outcome Parameters and Statistics

Median, range, and interquartile range were calculated for all continuous patient and case characteristics, and frequency with percentages for categorical

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variables. Primary outcome parameters were the median radiation exposure to patients and the two interventional cardiologists for each of the four study intervals. It was decided to only evaluate the two interventional cardiologists instead of all members of staff, due to the notably higher radiation exposure (closest to radiation source) and due to the fluctuation of other cath lab staff.

Physician and patient radiation exposure was compared between each of the study intervals using the Kruskal–Wallis test. To eliminate the impact of procedure type variation between study intervals, patient exposure was also compared between each of the four study intervals for two well-defined procedure types: atrial septal defect (ASD) device closure, as well as closure of the patent arterial duct (PDA), using the Kruskal–Wallis test. In addition, the incidence of radiation burns was compared between study intervals using the Chi-Square test. The incidence of radiation burns was compared between patients 18 years or older and younger patients using Fisher’s exact test. Cumulative air kerma and fluoroscopy time were compared between patients with and without radiation burns using the Mann–Whitney test.

RESULTS
Patient Radiation Exposure
Fluoroscopy times and cumulative air kerma are listed in Table II. There was a significant reduction in the median cumulative air kerma between the four study periods (710 mGy vs. 566 mGy vs. 498 mGy vs. 241 mGy, \( P < 0.001 \)), even though the overall
fluoroscopy times remained very similar (25 min vs. 26 min vs. 26 min vs. 23 min, \( P = 0.957 \)) (Figs. 2 and 3).

When analyzing the same procedure type, there was a significant reduction in the median cumulative air kerma for both, ASD device closure (1,051 mGy vs. 634 mGy vs. 452 mGy vs. 140 mGy, \( P < 0.001 \)), as well as PDA closure (328 mGy vs. 297 mGy vs. 301 mGy vs. 126 mGy, \( P = 0.001 \)) (Table II). In contrast, the fluoroscopy times did not change significant for either ASD closure (23 min vs. 18 min vs. 18 min vs. 13 min, \( P = 0.354 \)), or PDA closure (15 min vs. 17 min vs. 16 min vs. 15 min, \( P = 0.907 \)) (Table II).

**Physician (Interventionalists) Radiation Exposure**

Even though not reaching statistical significance, due to the small number of recordings in the most recent study interval, there was a definitive trend towards lower physician radiation exposure over the four study periods (137 mrem vs. 126 mrem vs. 108 mrem vs. 59 mrem, \( P = 0.15 \)) (Fig. 4).

**Radiation Burns**

A total of 15 patients were identified with radiation burns during the study period. After changing to the new follow-up protocol (phase 2 and 3), there were 109/808 (13%) patients with exposure ranging between 2,000 and 5,499 mGy, who received one follow-up phone call, 25/808 (3%) with exposure ranging between 5,500 and 8,999 mGy, who received three follow-up phone calls, and 16/808 (2%) with exposure above 9,000 mGy, who received three follow-up phone calls and had an additional clinic visit scheduled to evaluate for radiation burns. The lowest cumulative air

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**TABLE II. Radiation Dose (Cumulative Air Kerma) as well as Fluoroscopy Time for all Patients, as well as Patients with Isolated ASD or PDA Closure**

<table>
<thead>
<tr>
<th></th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cum. air kerma (R)</strong></td>
<td>(( n = 413 ))</td>
<td>(( n = 459 ))</td>
<td>(( n = 350 ))</td>
<td>(( n = 89 ))</td>
<td>(&lt;0.001)</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>(( n = 60 ))</td>
<td>(( n = 62 ))</td>
<td>(( n = 38 ))</td>
<td>(( n = 10 ))</td>
<td>0.957</td>
</tr>
<tr>
<td><strong>ASD closure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cum. air kerma (R)</td>
<td>(( n = 60 ))</td>
<td>(( n = 62 ))</td>
<td>(( n = 38 ))</td>
<td>(( n = 10 ))</td>
<td>(&lt;0.001)</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>(( n = 22 ))</td>
<td>(( n = 32 ))</td>
<td>(( n = 18 ))</td>
<td>(( n = 8 ))</td>
<td>0.354</td>
</tr>
<tr>
<td><strong>PDA closure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cum. air kerma (R)</td>
<td>(( n = 22 ))</td>
<td>(( n = 32 ))</td>
<td>(( n = 18 ))</td>
<td>(( n = 8 ))</td>
<td>(0.001)</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>(( n = 15 ))</td>
<td>(( n = 17 ))</td>
<td>(( n = 16 ))</td>
<td>(( n = 15 ))</td>
<td>0.907</td>
</tr>
</tbody>
</table>

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**Fig. 2.** Bar graphs documenting a significant reduction in median cumulative air kerma over the four study periods (\( P < 0.001 \)).

**Fig. 3.** Bar graphs documenting no significant changes in median total fluoroscopy time over the four study periods (\( P = 0.957 \)).

**Fig. 4.** Bar graph documenting a trend towards reduction in median physician exposure over the four study periods (\( P = 0.15 \)).
kerma of any patient during the study period with a radiation burn was 7,268 mGy. The lowest cumulative air kerma of any patient ever documented in the institution with a radiation burn was 3,810 mGy.

There was a slightly higher incidence of detected radiation burns from phase 1 (fluoroscopy time dependent) to phase 2–4 (radiation dose-dependent monitoring) (0.5% vs. 1.4%, P = 0.128), despite a reduction of fluoroscopy and acquisition frame rate. When just comparing phase 1 and phase 2 (immediately before and after changing the protocol), without including phase 3 and phase 4 that had additional methods of reducing radiation exposure, the detection rate of radiation burns increased significantly from 0.5 to 2% (P = 0.04).

There were only three burns noted during phases III and IV. In phase I, 23/26 (88%) patients with a dose exceeding 6,000 mGy did not receive any regular follow-up phone call or clinic visit because of the fluoroscopy not reaching the threshold of the original follow-up protocol of 120 min. Of the 15 burn patients, 12 (80%) were over the age of 18 years with a median body mass index (BMI) of 31 (22–60). The incidence of radiation burns was significantly higher in patients above 18 years when compared to those of younger age (0.2% vs. 3.8%, P < 0.001).

The median total air-kerma of patients with radiation burns was significantly higher in patient with radiation burns when compared to those without radiation burns (11,763 mGy vs. 544 mGy, P < 0.001). Equally, the median fluoroscopy time was significantly longer in patients with radiation burns when compared to those without radiation burns (80 min vs. 26 min, P < 0.001). Of 15 burn patients, 4 (27%) had multiple cardiac catheterizations during a one-month time period. Procedures performed on the patients who developed radiation burns included transcatheter Melody® Valve implantation, or attempt thereof (n = 7), treatment of arch obstructions (n = 2), complex pulmonary artery rehabilitation (n = 2), complex baffle leaks (n = 2), IVC filter removal (n = 1), as well as paravalvar leak occlusion (n = 1). Of those 15 patients that developed burns, 2 (13%) were third degree (Fig. 5) and 13 (87%) were first degree. None of the burns did manifest before the third week after exposure.

DISCUSSION

This study for the first time has clearly quantitated the reduction in radiation exposure that can be achieved through reduction of frame rates for acquisition and fluoroscopy, as well as the more liberal use of fluoroscopy recording instead of cine acquisition in patients with congenital and structural heart disease. With very few exceptions, such as infants with very fast heart rates, the operators in this study have not noticed any significant problem using a frame rate of 15 fps for both, fluoroscopy as well as cine acquisition. In fact, frame rates of 15 fps are now being used even for cine acquisition in the majority of cases (including smaller patients), and frame rates of 10 fps or less are adequate for less crucial imaging such as recordings of sizing balloon inflations, and others. While presets in the catheterization laboratory are important, their use has the disadvantage of not requiring the operator to make a conscious decision about the chosen frame rates. To this extent, operators may frequently be using higher frame rates of 30 fps even though they may find lower frame rates to be perfectly adequate. It therefore makes sense to change standard presets to lower frame rates, allowing then the operator to select higher frame rates for specific recordings in selected patients.

In this study, the two quantitatively largest improvements to patient dose were achieved with a reduction in the frame rate for fluoroscopy, as well as the introduction of important modifications and upgrades to the imaging equipment for phase 4. The superior noise reduction filter (SNRF, PureBrain®) introduced with upgrades to the Toshiba equipment allows noise reduction without image lag and an increase in the device contrast with standard fluoroscopy, while also resulting in a 50% noise reduction of digital acquisition. This has resulted in notable improvements in image quality and dose settings, with a reduction in patient and physician exposure of about 50% (phase 3 to phase 4). Furthermore, for the vast majority of recording, the image quality using fluoroscopy recording has been shown to be very similar to what can be achieved with cine acquisition. We only found very few exceptions where cine acquisition is still advantageous as
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As a conclusion, this study has documented the importance of dose-based follow-up protocols of patients undergoing transcatheter interventions for congenital and structural heart disease. It has quantitated the significant reductions to patient and staff exposure that can be achieved through frame rate reduction. Furthermore, it has shown the dose reduction that can be achieved through new, modified imaging equipment, which facilitates fluoroscopy recording at a similar image quality of conventional cine acquisition. Increasing staff, physician, and patient awareness of the importance of radiation protection efforts is a necessary and important endeavor.

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