Cardiac Catheterization

Effect of a Real-Time Radiation Monitoring Device on Operator Radiation Exposure During Cardiac Catheterization

The Radiation Reduction During Cardiac Catheterization Using Real-Time Monitoring Study

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Background—The Radiation Reduction During Cardiac Catheterization Using Real-Time Monitoring study sought to examine the effect of a radiation detection device that provides real-time operator dose reporting through auditory feedback (Bleeper Sv; Vertec Scientific Ltd; Berkshire, UK) on patient dose and operator exposure during cardiac catheterization. *Methods and Results*—Between January 2012 and May 2014, 505 patients undergoing coronary angiography, percutaneous coronary intervention, or both were randomized to use (n=253) or no use (n=252) of the Bleeper Sv radiation monitor. Operator radiation exposure was measured in both groups using a second, silent radiation exposure monitoring device. Mean patient age was 65±8 years, most patients (99%) were men, and 30% had prior coronary artery bypass graft surgery. Baseline clinical characteristics were similar in the 2 study groups. Radial access was used in 18% and chronic total occlusion percutaneous coronary intervention constituted 7% of the total procedures. Median procedure time was 17 (12–27) minutes for diagnostic angiography, 42 (28–70) minutes for percutaneous coronary intervention, and 27 (14–51) minutes in the overall study population, with similar distribution between the study groups. First (9 [4–17] versus 14 [7–25] μSv; P<0.001) and second (5 [2–10] versus 7 [4–14] μSv; P<0.001) operator radiation exposure was significantly lower in the Bleeper Sv group. Use of the device did not result in a significant reduction in patient radiation dose. The effect of the Bleeper Sv device on operator radiation exposure was consistent among various study subgroups.

Conclusions—Use of a real-time radiation monitoring device that provides auditory feedback can significantly reduce operator radiation exposure during cardiac catheterization.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01510353. (Circ Cardiovasc Interv. 2014;7:744-750.)

Key Words: cardiac catheterization ■ quality improvement ■ radiation

Radiation exposure is invisible, 1-3 but may cause injury of both the patient and the operator. 4-11 Advances in imaging equipment 12 along with operator education 13,14 can significantly reduce radiation exposure. Despite the use of specialized dosimetry equipment in some centers, the current gold standard for radiation surveillance is personal dosimetry, whereby

radiation values become available months after the procedure rather than immediately during the procedure.¹⁵ Real-time operator notification on radiation exposure could lead to behavioral modification that could further reduce radiation dose. The Radiation Reduction During Cardiac Catheterization Using Real-Time Monitoring (RadiCure) trial (ClinicalTrials.

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WHAT IS KNOWN

- Radiation exposure during cardiac catheterization has been significantly reduced by advancements in equipment technology and monitoring with personal dosimeters.
- Current monitoring devices record dose in a cumulative fashion and do not immediately provide information regarding radiation dose during a specific procedure.

WHAT THE STUDY ADDS

- The Bleeper Sv is a real-time monitoring device that produces a warning sound in response to excess radiation and also records radiation exposure.
- Use of the Bleeper Sv device in the RadiCure study resulted in a significant reduction in first and second operator exposure during cardiac catheterization procedures; however, patient dose was not significantly reduced.

gov Identifier: NCT01510353) sought to evaluate the effect of a real-time radiation monitoring device on operator exposure during cardiac catheterization.

Methods

Study Design

RadiCure was a randomized-controlled, single center, open label study that randomized patients undergoing coronary angiography, percutaneous coronary intervention (PCI), or both 1:1 to use or no use of the Bleeper Sv device (Vertec Scientific Ltd, Berkshire, United Kingdom). Radiation exposure was measured in both groups with a separate silent dosimeter. Because of the auditory feedback that the device provides to the operator, blinding of the operator was not feasible. Enrollment was performed when a research fellow was available and written informed consent was obtained from both the patient and the operators. All procedures were performed in 2 catheterization laboratories, one of which was equipped with a GE Innova system (GE Healthcare; Little Chalfont, United Kingdom) with 7.5 frames-per-second fluoroscopy capability and the other one with a Philips Allura Xper FD20 system (Philips Healthcare; Amsterdam, Netherlands) with 15 frames-per-second fluoroscopy capability. Patient and operator (first and second) exposure was recorded at the end of diagnostic catheterization and PCI and compared between the study groups (Figure 1). The effect of the device was assessed separately in groups where increased radiation exposure is typically expected (chronic total occlusion [CTO] interventions, radial access intervention, prior coronary artery bypass graft surgery cases, cases with increased patient dose, patients with high body mass index, and different fluoroscopy frame-rate settings). The procedures were performed by 18 operators (16 fellows and 2 attendings), all of whom received similar training on equipment use and radiation safety (radiation safety lecture at beginning of the rotation and feedback sessions with the attending physicians).

Real-Time Radiation Monitoring Device

Real-time monitoring was achieved with a radiation detection device that provides auditory feedback (Bleeper Sv; Figure 2, Movie I in the Data Supplement). The Bleeper Sv sounds approximately every 15 minutes as a result of background radiation; the bleep rate increases with higher radiation levels. Moreover, the device provides cumulative radiation exposure of the operator. The Bleeper Sv device was

placed in the chest pocket outside the operator's lead apron before cardiac catheterization (Figure 2). The device was used in addition to standard protective equipment, including protective lead apron with thyroid shield, lead glasses, ceiling-suspended shield, and table-suspended drapes.

Statistical Analysis

Preliminary data from 55 procedures where the Bleeper Sv was used demonstrated an average first operator exposure of $20\pm20~\mu Sv$. Power analysis was performed based on operator exposure rather than on patient dose because the study's primary end point was operator exposure. Based on these preliminary measurements, a sample size of 505 patients was required to provide 80% power to detect a 25% reduction in first operator radiation exposure.

Continuous data were reported as mean±standard deviation (normally distributed data) or median and interquartile range (non-normally distributed data) and compared using t test or Wilcoxon rank-sum test, as appropriate. Categorical data were presented as frequencies or percentages and compared using χ^2 or Fisher exact test, as appropriate. To adjust for correlation of radiation exposure with operator-related factors, we used generalized linear mixed models to evaluate the effect of the Bleeper Sv device on operator radiation exposure. The fixedeffects portion of each model was assigned to use of Bleeper Sv device versus control, and the random effects portion of each model was assigned to the patient nested within 1 of 18 operators. First and second operator radiation exposure were significantly positively skewed and, therefore, were normalized with a logarithmic transformation.¹⁶ A 2-sided P value of <0.05 was considered significant for all analyses, which were performed using JMP 11 (SAS Institute, Cary, North Carolina) and SPSS 21 (IBM, New York, New York) for Windows.

Results

Patient Population

Between January 2012 and May 2014, 505 patients undergoing coronary angiography and PCI at our institution were randomized to Bleeper Sv or no real-time radiation monitoring. The baseline patient characteristics are summarized in Table 1. Mean age was 65±8 years, and most patients were men (99%). Patients had high frequency of diabetes mellitus (52%), prior PCI (43%), and prior coronary artery bypass graft surgery (30%). Patient characteristics were similar in the 2 study groups; however, patients in the Bleeper Sv group were older (66±8 versus 64±8 years; *P*=0.021), less likely to be

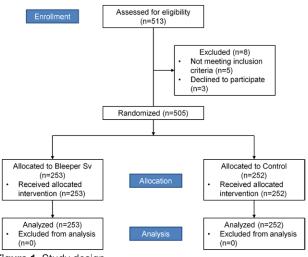


Figure 1. Study design.







Figure 2. The Bleeper Sv radiation monitoring device (Vertec Scientific Ltd, Berkshire, UK).

men (98% versus 100%; *P*=0.030), and had higher frequency of peripheral arterial disease (21% versus 14%; *P*=0.028).

Procedural Outcomes

Most procedures (64%) were diagnostic coronary angiograms, followed by diagnostic angiograms combined with PCI (25%), and PCI only procedures (11%), with similar distribution between the study groups (Table 2). Radial access was used in 18% and CTO PCI constituted 7% of the total procedures. Median procedure time was 17 (12–27) minutes for diagnostic angiography, 42 (28–70) minutes for PCI, and 27 (14–51) minutes in the overall study population, with similar distribution between the study groups.

First operator radiation exposure was significantly lower in the Bleeper Sv compared with the control group (9 [4–17] versus 14 [7–25] μ Sv; P<0.001; 36% relative reduction). First operator radiation exposure was lower in the Bleeper Sv group both for diagnostic angiography (7 [4–11] versus 10 [5–20] μ Sv; P<0.001) and for PCI (11 [4–19] versus 14 [6–22] μ Sv; P=0.323; Figure 3). The lower first operator radiation exposure in the Bleeper Sv group was consistent across subgroups, such as patients undergoing CTO PCI, patients with prior coronary artery bypass graft surgery, cases performed using radial access, patients with above median air kerma (AK) radiation exposure, patients with above median body mass index, and cases performed with different fluoroscopy equipment (Figure 4A). No significant interaction was noted between randomization and CTO PCI (P=0.532), prior coronary artery bypass graft surgery (P=0.111), radial access (P=0.360), AK radiation dose (P=0.469), body mass index (P=0.266), and x-ray system type (P=0.876). The effect of Bleeper Sv on first operator exposure was also similar during consecutive periods of the study (Figure 5) and demonstrated little intraoperator variability (Figure 6).

Similarly, second operator radiation exposure was significantly lower in the Bleeper Sv group (5 [2–10] versus 7 [4–14] μ Sv; P<0.001; 29% relative reduction; Figure 3). Second operator radiation exposure was lower in the Bleeper Sv group both for diagnostic angiography (4 [2–8] versus 7 [3–11] μ Sv; P<0.001) and for PCI (4 [2–12] versus 6 [3–16] μ Sv; P=0.197). The effect of Bleeper Sv on second operator exposure remained consistent across various subgroups (Figure 4B).

Use of the device did not result in a statistically significant reduction in patient AK and dose area product: 0.855 (0.580–1.507) versus 0.989 (0.610–1.802) Gray, P=0.153 for AK and 76.68 (52.98–133.53) versus 84.61 (55.37–161.20) Gray cm², P=0.125 for dose area product. Fluoroscopy time

Table 1. Clinical Characteristics of the Study Patients

Variable	Overall (n=505)	Bleeper Sv (n=253)	Control (n=252)	<i>P</i> Value
Age, y	65±8	66±8	64±8	0.021
Men, %	99	98	100	0.030
Ethnicity, %				
White	72	73	71	0.606
Black	23	24	23	
Hispanic	3	2	4	
Other	2	1	2	
Weight, kg	98±22	98±23	97±20	0.850
Height, m	1.77±0.08	1.76±0.08	1.78±0.07	0.218
BMI, kg/m ²	31±6	31±7	31±6	0.581
Clinical presentation, %				
Stable angina	34	34	34	0.614
Unstable angina	8	10	6	
NSTEMI	16	16	16	
Other*	42	40	44	
Diabetes mellitus, %	54	57	52	0.256
Hyperlipidemia, %	92	92	92	0.989
Hypertension, %	91	91	91	0.988
Current smoking, %	29	29	28	0.866
Prior MI, %	37	35	38	0.406
Prior CHF, %	38	38	38	0.955
Prior PCI, %	43	43	42	0.681
Prior CABG, %	30	28	32	0.366
Cerebrovascular disease, %	10	11	10	0.477
Peripheral arterial disease, $\%$	18	21	14	0.028

Categorical variables are presented as percentages and continuous variables as mean±standard deviation. BMI indicates body mass index; CABG, coronary artery bypass graft surgery; CHF, congestive heart failure; MI, myocardial infarction; NSTEMI, non–STR-elevation myocardial infarction; and PCI, percutaneous coronary intervention.

*Other indications included cardiomyopathy, positive stress test, valvular heart disease, arrhythmia, and research studies.

Table 2. Procedural Characteristics and Outcomes

Variable	Overall (p. 505)	Bleeper Sv	Control	DValue
Variable	(n=505)	(n=253)	(n=252)	<i>P</i> Value
Procedure type, %				
Diagnostic only	64	65	64	0.852
PCI only	11	11	10	
Diagnostic and PCI	25	24	26	
Radial access, %	18	17	19	0.549
CTO PCI, %	7	6	8	0.591
Use of radiopaque drape, %	29	30	27	0.493
Procedure time, min				
Diagnostic	17 (12–27)	16 (11–27)	19 (11–27)	0.176
PCI	42 (28–70)	42 (28–69)	42 (30–72)	0.787
Overall	27 (14–51)	26 (14–50)	29 (14–52)	0.249
Number of cine-angiography runs				
Diagnostic	11 (9–12)	9 (7–11)	11 (10–14)	0.033
PCI	25 (11–37)	15 (11–29)	34 (26–47)	0.017
Overall	14 (11–30)	14 (9–29)	14 (11–36)	0.394
First operator exposure, μSv				
Diagnostic	8 (4–16)	7 (4–11)	10 (5–20)	< 0.001
PCI	12 (4–21)	11 (4–19)	14 (6–22)	0.323
Overall	10 (5–22)	9 (4–17)	14 (7–25)	< 0.001
Second operator exposure, μSv				
Diagnostic	5 (2–9)	4 (2–8)	7 (3–11)	< 0.001
PCI	6 (3–14)	4 (2–12)	6 (3–16)	0.197
Overall	7 (3–12)	5 (2–10)	7 (4–14)	< 0.001
Patient AK radiation dose, Gray				
Diagnostic	0.747 (0.505-0.997)	0.728 (0.493-0.976)	0.786 (0.511-1.053)	0.189
PCI	1.389 (0.713-2.163)	1.25 (0.676–2.071)	1.410 (0.749–2.165)	0.631
Overall	0.908 (0.602-1.636)	0.855 (0.58-1.507)	0.989 (0.610-1.802)	0.153
Patient DAP radiation dose, Gray cm ²				
Diagnostic	64.10 (46.68-86.27)	63.17 (45.42-83.36)	66.26 (47.39-89.64)	0.269
PCI	104.47 (60.65–185.14)	104.83 (58.49-183.75)	104.11 (60.23–193.86)	0.511
Overall	80.37 (54.79-145.99)	76.68 (52.98-133.53)	84.61 (55.37-161.20)	0.125
Fluoroscopy time, min				
Diagnostic	3.7 (1.9–7.1)	3.3 (1.8-7.1)	4.0 (2.0-7.2)	0.311
PCI	9.7 (5.2–18.1)	9.2 (5.3-17.4)	10.2 (4.9–18.8)	0.772
Overall	6.2 (2.5–12.5)	6.0 (2.2-12.3)	6.6 (2.9–13.0)	0.223
Contrast volume, mL				
Diagnostic	100 (84–129)	100 (80–126)	105 (85–130)	0.163
PCI	154 (83–239)	167 (86–250)	144 (80–233)	0.450
Overall	125 (90–200)	122 (87–192)	125 (90–211)	0.184

Categorical variables are presented as percentages and continuous variables as median (interquartile range). AK indicates air kerma; CTO, chronic total occlusion; DAP, dose area product; and PCI, percutaneous coronary intervention.

(6.0 [2.2-12.3] versus 6.6 [2.9-13.0] minutes, P=0.223) and contrast utilization (122 [87–192] versus 125 [90–211] mL, P=0.184) were numerically lower in the Bleeper Sv group, but the difference did not reach statistical significance (Table 2).

Discussion

The RadiCure is the first prospective randomized trial to evaluate use of a real-time radiation monitoring device during

diagnostic angiography and PCI, showing significantly lower first and second operator radiation exposure.

A challenge with radiation protection is that radiation is invisible. 1-3 Use of a radiation detection device can real-time visulization of radiation exposure, thus enabling operator behavior modification in response to the auditory feedback provided by the device. The operator can take several actions to reduce radiation exposure, such as (1) reducing the frame

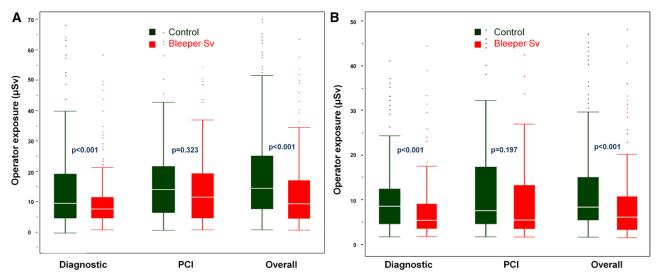


Figure 3. Effect of Bleeper Sv on first (A) and second (B) operator exposure.

rate (although the lowest possible frames-per-second fluoroscopy for each x-ray machine was used in our study); (2) decreasing fluoroscopy time; (3) repositioning the patient to maximize the distance from the x-ray tube, minimize the distance from the image intensifier, and reduce angulation; (4) repositioning the operator as far as feasible from the patient; (5) adjusting the position of the radiation shield; and (6) using additional shielding, such as disposable radioabsorbent drapes.¹⁷ The relative contribution of each of the above elements in the reduction of operator radiation exposure observed in RadiCure cannot be determined; however, fluoroscopy time was numerically lower in the Bleeper Sv group, whereas use of disposable radiation shields was similar in the 2 study groups. Image intensifier angulation can significantly affect radiation scatter, 18 and part of the operator radiation reduction shown in RadiCure may have resulted from repositioning the C-arm to less angulated projections.

Decreasing fluoroscopy frame rate is an easy, yet efficient way to reduce the radiation exposure. A recent randomized controlled trial of 7.5 versus 15 frames-per-second fluoroscopy during transradial coronary angiography and intervention demonstrated a 30% (P<0.0001) relative reduction in operator exposure and 19% (P=0.022) relative reduction in patient

dose area product.¹⁹ Use of x-ray equipment with novel radiation protocols can also reduce radiation exposure. Wassef et al studied a novel radiation reduction protocol (EPO; Philips, Netherlands) that reduces detector dose rate in acquisition imaging, decreases the frame rate, fine tunes the x-ray parameters (peak tube voltage, cathode current, spectral filter) to the examination and patient's size, and increases the thickness of the x-ray beam spectral filters.¹² Implementation of the EPO protocol resulted in a 35% (P<0.0001) reduction in patient AK radiation dose with 15 frames-per-second fluoroscopy and a 62% reduction (P<0.0001) with 7.5 frames-per-second fluoroscopy. The effect of the Bleeper Sv device in reducing operator radiation exposure in our study was consistent, whether 7.5 or 15 frames-per-second fluoroscopy was used (Figure 4).

Fluoroscopy time depends on both operator and procedurerelated factors, as shown in a recent report from the National Cardiovascular Data Registry.²⁰ Variables that were associated with higher fluoroscopy times for diagnostic catheterization were brachial arterial access (6.0 minutes of added fluoroscopy time), radial access (3.6 minutes), congenital heart disease (3.2 minutes), concomitant right heart catheterization (2.7 minutes), and university hospital setting (2.6 minutes). For PCI, coronary dissection or perforation (7.7 minutes),

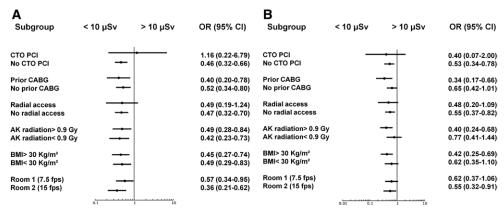


Figure 4. Effect of the Bleeper Sv on first (A) and second (B) operator radiation exposure across various subgroups. AK indicates air kerma; BMI, body mass index; CABG, coronary artery bypass graft surgery; CTO, chronic total occlusion; OR (95% CI), odds ratios with 95% confidence intervals; and PCI, percutaneous coronary intervention.

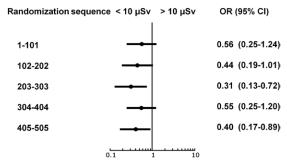


Figure 5. Effect of the Bleeper Sv on first operator exposure during consecutive study periods. OR (95% CI) indicates odds ratios with 95% confidence intervals.

use of atherectomy, thrombectomy, or extraction catheter or laser (7.1 minutes), brachial artery access (7.2 minutes), and number of lesions intervened upon (4.9 minutes) were the factors associated with the greatest prolongation of fluoroscopy time. After accounting for patient characteristics and procedure complexity, operator and hospital-level factors explained nearly 20% of the variation in fluoroscopy time, highlighting the importance of modifying operator behavior. Experienced operators have been shown to use less fluoroscopy in complex procedures, such as CTO interventions.²¹ RadiCure demonstrates that using devices that provide real-time radiation exposure feedback can help the operator adopt safer radiation practices. This was achieved in a contemporary, real-life setting, among unselected patients, using a low cost (<\$1000) device, that can be used with any x-ray system, without requiring upfront capital investment or specialized setup.

The reduction in operator exposure observed in the RadiCure study is likely to translate into a decreased risk for long-term adverse clinical events. Radiation side effects are often classified as deterministic or stochastic. 15,22,23 Deterministic effects are thought to occur in a dose–response relationship when exposure exceeds a certain limit (ie, skin injury). Stochastic

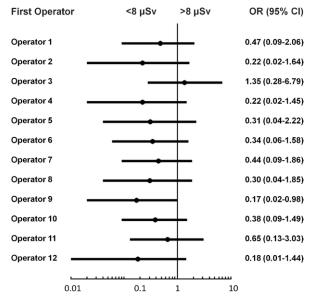


Figure 6. Effect of the Bleeper Sv on first operator exposure during diagnostic catheterization. Operators that performed >20 procedures throughout the study were included. OR (95% CI) indicates odds ratios with 95% confidence intervals.

effects are all-or-none events that occur more frequently with higher exposure rates (cancer, pregnancy complications). Current radioprotection assumes a linear-no threshold dose-effect relationship, whereby no safe dose exists and all doses add up in determining cancer risk.²⁴ It is estimated that radiation exposure results in a lifetime attributable cancer risk of ≈1:100 for high-volume operators.^{7,19,24} Based on the RadiCure trial results, use of monitoring devices during catheterization procedures is expected to reduce this risk by approximately one third, a large and clinically meaningful effect.

Unlike operator exposure, use of the Bleeper Sv device did not result in statistically significant reduction in patient radiation dose. Some procedural adjustments in response to real-time radiation feedback (such as use of radiation shields and operator repositioning) can protect the operator, but not the patient. In addition, RadiCure was underpowered to detect reductions in patient radiation dose.

Other real-time monitoring devices exist and can assist with reducing operator's radiation exposure; however, their efficacy in the catheterization laboratory setting has not been demonstrated in randomized controlled trials. For example, DoseAware (Philips) is a personal dosimeter, which is worn by staff and wirelessly connects to a base station that records radiation exposure and provides visual feedback to the operator. The extent of radiation exposure reduction that can be achieved with these devices remains to be determined. Radiation exposure depends on the operator-related factors and efficient use of the protective equipment. Radiation safety training can affect the average exposure per case and could in part be responsible for the low operator exposure observed in the RadiCure study.

Our study is limited by its single center design. Blinding of patients and operators on use of the Bleeper Sv device was not feasible; therefore, a Hawthorne effect is possible. The study was powered for operator exposure, not patient radiation dose. The response to the device's auditory feedback was at the discretion of the operator and no prespecified course of action was dictated. As is typical of veteran populations, most of the study patients were men, limiting extrapolation to women, although it is unlikely that significant sex differences exist in radiation exposure. Only diagnostic coronary angiography and PCI cases were included in the study; whether the study results apply to other procedure types (such as peripheral procedures that result in greater radiation exposure)25 remains to be determined. Future studies are important to validate the results of the RadiCure study and further characterize the effect of real-time monitoring on operator and patient radiation outcomes.

In conclusion, the RadiCure study demonstrated that use of a real-time monitoring device during cardiac catheterization resulted in decreased first and second operator exposure (by 36% and 29%, respectively), supporting expanded use of such devices in the cardiac catheterization laboratory.

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Effect of a Real-Time Radiation Monitoring Device on Operator Radiation Exposure During Cardiac Catheterization: The Radiation Reduction During Cardiac Catheterization Using Real-Time Monitoring Study

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