

MINI-FOCUS ISSUE: RADIATION DOSE REDUCTION
Clinical Research

Radiation Dose Reduction in the Cardiac Catheterization Laboratory Utilizing a Novel Protocol

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Objectives This study reports the results a novel radiation reduction protocol (RRP) system for coronary angiography and interventional procedures and the determinants of radiation dose.

Background The cardiac catheterization laboratory is an important source of radiation and should be kept in good working order with dose-reduction and monitoring capabilities.

Methods All diagnostic coronary angiograms and percutaneous coronary interventions from a single catheterization laboratory were analyzed 2 months before and after RRP implementation. The primary outcome was the relative dose reduction at the interventional reference point. Separate analyses were done for conventional 15 frames/s (FPS) and at reduced 7.5 FPS post-RRP groups.

Results A total of 605 patients underwent coronary angiography (309 before RRP and 296 after RRP), with 129 (42%) and 122 (41%) undergoing percutaneous coronary interventions before and after RRP, respectively. With RRP, a 48% dose reduction (1.07 ± 0.05 Gy vs. 0.56 ± 0.03 Gy, $p < 0.0001$) was obtained, 35% with 15 FPS RRP (0.70 ± 0.05 Gy, $p < 0.0001$) and 62% with 7.5 FPS RRP (0.41 ± 0.03 Gy, $p < 0.001$). Similar dose reductions for diagnostic angiograms and percutaneous coronary interventions were noted. There was no change in the number of stents placed or vessels intervened on. Increased dose was associated with male sex, radial approach, increasing body mass index, cine runs, and frame rates. Using a multivariable model, a 48% relative risk with RRP ($p < 0.001$), 44% with 15 FPS RRP and 68% with 7.5 FPS RRP was obtained.

Conclusions We demonstrate a highly significant 48.5% adjusted radiation dose reduction using a novel algorithm, which needs strong consideration among interventional cardiology practice. (J Am Coll Cardiol Intv 2014;7:550–7) © 2014 by the American College of Cardiology Foundation

Ionizing radiation makes invasive cardiology procedures such as coronary angiography, percutaneous coronary intervention (PCI), and electrophysiologic diagnostics and therapeutics possible (1). The cardiac catheterization laboratory is an important source of medical radiation (2). Radiation risks can be thought of as deterministic (effects after exceeding certain threshold, e.g., skin burns) or stochastic (a risk of an outcome is proportional to the dose received, e.g., malignancy or teratogenicity) (3). Reducing the radiation exposure in the cardiac catheterization laboratory is important, especially as procedures are becoming more complex (2). Unfortunately, once all confounding factors are accounted for, decreasing the radiation dose generally results in lower image quality as there is decreased signal-to-noise ratio (1). The purpose of our study was to assess the radiation dose reduction associated with a new radiation reduction protocol (RRP), and to quantify any changes in the throughput of cases through the catheterization laboratory after the dose reduction protocol was implemented.

Methods

Intervention. In the first 2 weeks of May 2012, at our institution we upgraded the cardiac catheterization laboratories (Philips Allura Xper, Royal Philips Electronics, Amsterdam, the Netherlands) with the novel ECO protocol (Fig. 1). The ECO settings are technical changes in the EPX (or examination programmed x-ray parameters) of the Allura Xper systems where X-ray parameters (e.g., the peak tube voltage, the cathode current, spectral filter) are fine-tuned to the specific examination type and patient size. The technical changes involved increasing the thickness of x-ray beam spectral filters for acquisition imaging, reducing the frame rates (7.5 frames/s [FPS]), reducing detector dose rate in acquisition imaging, and setting the default fluoroscopy dose rate mode from normal to low or a combination of these changes.

Data collection. We reviewed data of consecutive patients who underwent cardiac catheterization procedures at 1 of our institution's 3 cardiac catheterization laboratories 2 months prior to RRP implementation and 2 months after implementation. A single laboratory was chosen to maintain consistency and remove potential machine-related differences. There was no change in operators or seasonal differences during the investigation period. Institutional ethics board approval was obtained. Patient demographic information and biometric data (height, weight, body mass index [BMI]), which may affect radiation exposure, was obtained from the catheterization laboratory database. Arterial access (radial vs. femoral) was documented. Procedural details including total fluoroscopic time and cine angiographic acquisition runs were recorded. The number of vessels intervened upon and number of stents placed was also

recorded. The pre-RRP fluoroscopic and cineangiographic images were all acquired in 15 FPS. However, once the RRP was established, the option of 7.5 FPS or 15 FPS acquisition was available at the operator's discretion (Fig. 2A).

Data analysis. The primary outcome of this study was air kerma—radiation dose reduction as measured at the interventional reference point ($K_{A,R}$) 15 cm from the isocenter of the beam. Mean radiation exposure before and after RRP implementation was recorded. Subgroup analysis was done for patients undergoing only diagnostic angiography as well as those undergoing PCI (Fig. 2A). Furthermore, separate analyses were done for RRP performed at conventional frame rates (15 FPS) and reduced frame rates (7.5 FPS). The chi-square test was used to test for statistical significance for categorical variables. Continuous variables were expressed as mean \pm SD or mean \pm SE and analyzed with *t* test or Mann-Whitney *U* test for statistical significance. Univariate analysis was performed using SAS (version 9.2, SAS, Cary, North Carolina) to assess for predictors of increased $K_{A,R}$ (sex, BMI, access approach, fluoroscopy time, number of cine runs, PCI (yes/no), RRP use, and frame rate) for all studies, angiography alone, PCI alone, and the previously listed studies done at 15 FPS and 7.5 FPS. Beta coefficients of variance with standard errors were calculated. A multivariate linear regression analysis was performed with the preceding variables and an adjusted $K_{A,R}$ (mean \pm SE) was reported with percentage of reduction after RRP.

Abbreviations and Acronyms

BMI = body mass index

FPS = frames per second

$K_{A,R}$ = air kerma at the interventional reference point

PCI = percutaneous coronary intervention

RRP = radiation reduction protocol

Results

Patient characteristics. A total of 605 consecutive patients underwent diagnostic angiography and/or PCI at a single cardiac catheterization laboratory at St. Boniface Hospital, Winnipeg, Manitoba, Canada, a major tertiary cardiac care referral center. A total of 309 patients were included prior to RRP implementation (March 1, 2012, to April 30, 2012). Of these, 180 underwent diagnostic angiography and 129 underwent PCI (Fig. 2A). A 2-week implementation period was undertaken. There were 296 patients in the post-RRP group (May 18, 2012, to July 22, 2012); of those, 174 underwent diagnostic angiograms and 122 underwent PCI. Of the post-RRP cohort, 160 patients had their studies completed at traditional 15 FPS and 136 patients underwent studies at 7.5 FPS (Fig. 2B). The choice of frame rate was at the discretion of the operator. Of the 67 diagnostic angiograms done at 7.5 FPS in the post-RRP group, only 2 studies required more than one-third of the cineangiograms at 15 FPS to improve visualization. For PCI in the post-

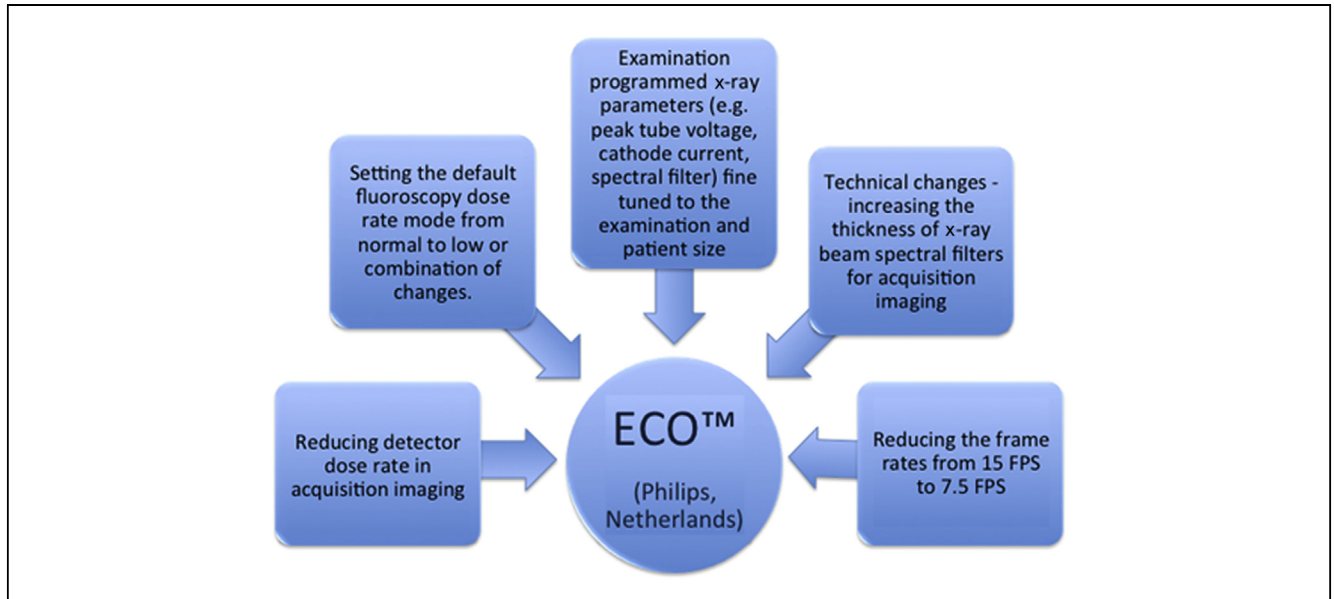


Figure 1. Components of ECO

Components of ECO consisted technical changes as well as programmable changes. The option of reducing the frame rate further from 15 frames/s (FPS) to 7.5 FPS was available to the operator.

RRP group, of 55 patients who were done at 7.5 FPS, 4 required more than one-third of their cineangiographic runs to be done at 15 FPS. For studies that were at 15 FPS, both angiograms and PCI, there were no studies that required increased frame rate to 30 FPS.

With regard to baseline characteristics, there were no significant differences between pre-RRP and post-RRP patients in terms of age, BMI, number of patients undergoing PCI, and number undergoing radial procedures.

There were no differences among those post-RRP patients whose procedures were done under 15 FPS and those at 7.5 FPS compared with pre-RRP patients for these variables (Table 1). There was, however, a statistically significant higher percentage of male patients in the post-RRP group than in the pre-RRP group (59% pre-RRP vs. 69% post-RRP, $p = 0.008$) (Table 1).

Radiation dose reduction (unadjusted). In the pre-RRP cohort for all patients, the mean $K_{A,R}$ was 1.07 ± 0.05 Gy

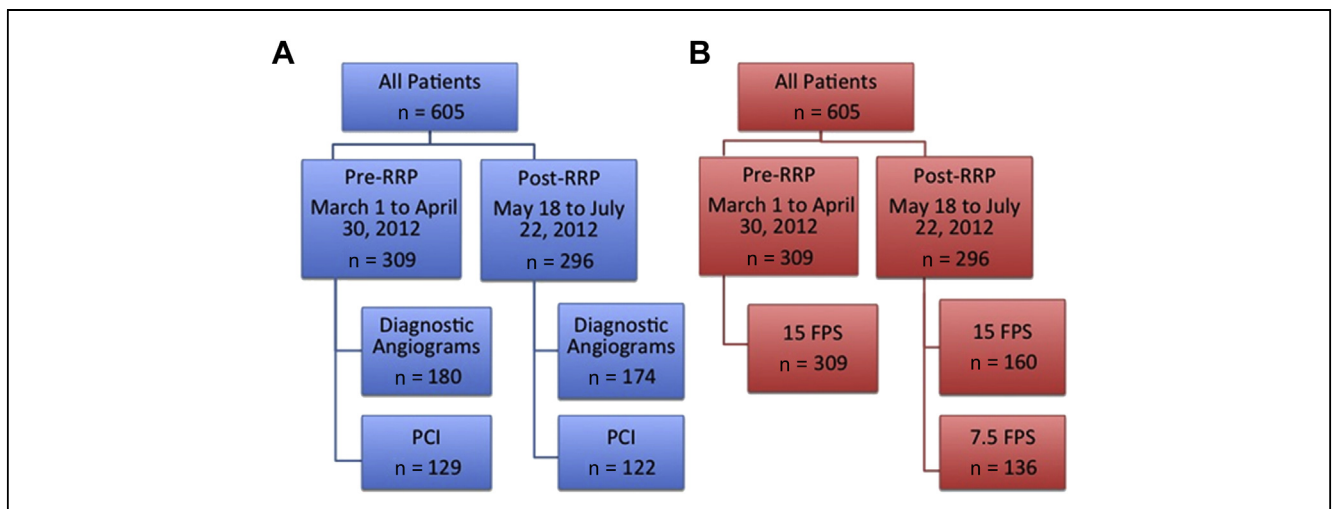


Figure 2. Patients Included in Trial

Patients were included in this study pre-RRP (A) or post-RRP (B) implementation. At the operators' discretion, studies could be performed at 15 FPS or 7.5 FPS. FPS = frames per second; PCI = percutaneous coronary intervention; RRP = radiation reduction protocol.

Table 1. Baseline Demographics for the Complete Pre-RRP and Post-RRP Patients and the 15 FPS and 7.5 FPS Post-RRP Subgroups

	Pre-RRP (n = 309)	Post-RRP (n = 296)		Post-RRP 15 FPS (n = 160)		Post-RRP 7.5 FPS (n = 136)	
				p Value		p Value	
Age, yrs	66 ± 13	66 ± 12	0.63	66 ± 12	0.72	66 ± 12	0.68
Male	182 (59)	205 (69)	0.01	116 (72)	<0.01	89 (65)	0.22
Weight, kg	84.0 ± 18.8	86.6 ± 23.4	0.13	85.7 ± 21.3	0.37	87.6 ± 25.8	0.09
BMI, kg/m ²	29.2 ± 6.0	29.7 ± 6.9	0.34	29.2 ± 6.4	0.99	30.3 ± 7.3	0.10
Radial approach	158 (51)	157 (53)	0.64	76 (47)	0.46	81 (59)	0.10
PCI	129 (41)	122 (41)	0.89	67 (42)	0.98	55 (40)	0.80
Mean stents/PCI	1.84 ± 0.06	2.05 ± 0.08	0.51	2.21 ± 0.12	0.19	1.85 ± 0.10	0.72
Mean vessels/PCI	1.20 ± 0.02	1.19 ± 0.02	0.67	1.21 ± 0.04	0.98	1.16 ± 0.04	0.43
Fluoroscopy time, min	8.44 ± 0.49	8.90 ± 0.50	0.31	9.52 ± 0.76	0.23	8.16 ± 0.70	0.67
Mean cine runs	16.2 ± 0.6	18.0 ± 0.7	0.07	18.4 ± 1.1	0.23	17.6 ± 0.9	0.07

Values are mean ± SD, mean ± SE, or n (%). All comparisons were made to pre-RRP values for all p values. Age, weight, and BMI expressed as mean ± SD. Mean stents and vessels intervened upon per PCI procedure and mean fluoroscopy time and cine runs expressed as mean ± SE.

BMI = body mass index; FPS = frames per second; PCI = percutaneous coronary intervention; RRP = radiation reduction protocol.

(Fig. 3). There was a highly statistically significant 48% reduction in $K_{A,R}$ for all patients in the post-RRP cohort at 0.56 ± 0.03 Gy ($p < 0.0001$). Compared with the pre-RRP cohort, there was a statistically significant 35% dose reduction in the post-RRP 15 FPS, 0.70 ± 0.05 Gy ($p < 0.0001$) and a 62% dose reduction, 0.41 ± 0.02 Gy ($p < 0.0001$) in the post-RRP 7.5 FPS cohort.

The dose reduction afforded by the RRP was maintained in the angiography-alone subgroup (48%, 0.67 ± 0.03 Gy

pre-RRP vs. 0.35 ± 0.02 Gy post-RRP, $p < 0.0001$). Similarly, for patients undergoing PCI, there was a 46% reduction in $K_{A,R}$ (1.61 ± 0.09 Gy pre-RRP vs. 0.87 ± 0.06 Gy post-RRP, $p < 0.0001$).

Procedural characteristics. The mean fluoroscopy time was 8.44 ± 0.49 min for pre-RRP patients and was similar for post-RRP patients, 8.90 ± 0.50 min ($p = 0.31$). Similar fluoroscopy times were present in both the post-RRP 15 FPS and 7.5 FPS groups (Table 1). There were no differences

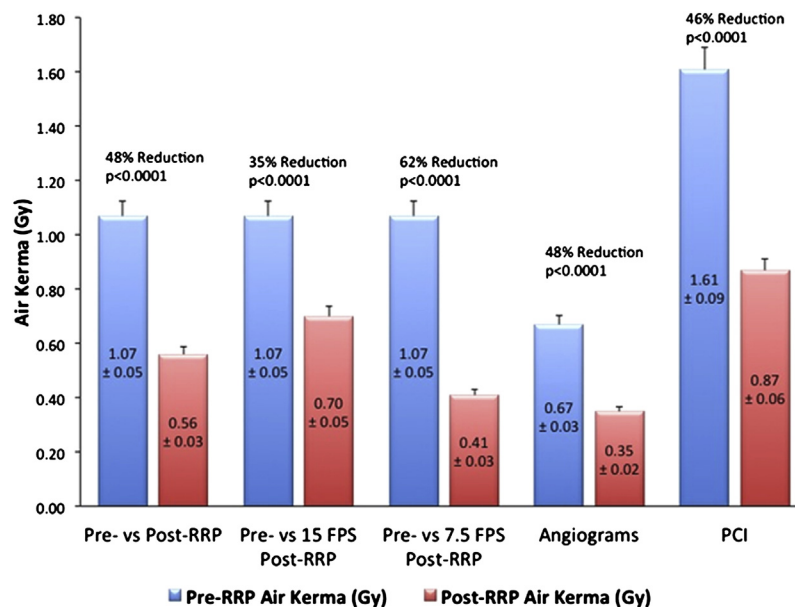


Figure 3. Unadjusted Radiation Dose ($K_{A,R}$) at the Interventional Reference Point

Radiation dose at the interventional reference point (air kerma, $K_{A,R}$) for patients pre- and post-RRP implementation and for subgroups of frame rates, angiograms alone, and PCI alone. Abbreviations as in Figure 2.

between fluoroscopy times between the pre- and post-RRP angiography groups and the pre- and post-RRP PCI groups (Table 2). There was a nonstatistically significant trend toward a higher number of cine runs post-RRP, however. The mean \pm SD number of cine runs prior to RRP was 16.2 ± 0.6 compared with 18.0 ± 0.7 ($p = 0.07$) in all patients post-RRP, 18.4 ± 1.1 ($p = 0.23$) for those undergoing procedures at 15 FPS, and 17.6 ± 0.9 ($p = 0.07$) and for those undergoing procedures at 7.5 FPS. A statistically significant increase in the number of cine runs was noted in the angiography group and a nonstatistically significant trend toward more cine runs in the PCI group (Table 2).

With regard to the catheterization laboratory throughput, there was no change in the relative proportion of patients undergoing PCI before and after RRP (42% vs. 41%, $p = 0.89$), which was also noted in the 15 and 7.5 FPS subgroups of the post-RRP cohort. The mean number of stents placed per PCI procedure was mildly increased (Fig. 4). There were a mean of 1.84 ± 0.06 stents placed per PCI procedure before RRP versus 2.05 ± 0.08 after RRP ($p = 0.03$). The post-RRP 15 FPS group had slightly statistically significantly more stents placed per PCI procedure, 2.21 ± 0.12 ($p = 0.002$), whereas the 7.5 FPS group did not 1.85 ± 0.10 ($p = 0.62$). The number of vessels intervened upon per PCI procedure was not different between the groups. **Univariate and multivariate adjustments.** Statistically significant univariate predictors of increased $K_{A,R}$ at the interventional reference point for the full population included male sex, increased BMI, higher fluoroscopy time, PCI procedure, and number of cine runs (Table 3). The use of the RRP protocol and use of 7.5 FPS as compared to 15 FPS were statistically significant predictors of decreased $K_{A,R}$. Radial access was a predictor that increased $K_{A,R}$ for the whole population as well as the PCI-alone group; however, radial access was not a statistically significant predictor of increased $K_{A,R}$ for the angiography alone group.

A multivariate linear regression model was created to assess the reduction in $K_{A,R}$ with the variables sex (male),

BMI, fluoroscopy time, PCI (yes/no), cine runs, radial access (yes/no), RRP use (yes/no), and frame rate (7.5 vs. 15 FPS) to correct for baseline difference. The adjusted overall ($n = 605$) dose reduction was 48% (adjusted mean $K_{A,R}$ 0.98 ± 0.04 vs. 0.51 ± 0.03 Gy after RRP) (Fig. 5). The adjusted $K_{A,R}$ reduction was 49% for angiograms alone (0.61 ± 0.03 vs. 0.31 ± 0.02 Gy) and 50% for PCI (1.52 ± 0.07 vs. 0.76 ± 0.05 Gy). The adjusted reductions for post-RRP 15 FPS and 7.5 FPS were 44% and 68%, respectively (Fig. 5). The distribution of residuals was examined for all models presented in this manuscript. Several model diagnostic plots have confirmed that the residuals for all models appear to be independent, normally distributed, with an approximate mean of 0 and constant variance.

Discussion

In this single-center study of consecutive patients who underwent coronary angiography and PCI, we were able to demonstrate a significant reduction in the radiation dose with the use of RRP, a dose reduction technology. The magnitude of overall (all patients of both 15 and 7.5 FPS subgroups combined) $K_{A,R}$ reduction was 48% adjusted for other variables. An even greater 68% adjusted $K_{A,R}$ dose reduction was obtained when using RRP at 7.5 FPS. These $K_{A,R}$ dose reductions were present both in patients undergoing angiography and undergoing PCI.

Equally important to the radiation dose reduction was the fact that catheterization laboratory volumes and interventions did not decrease during this time. The percentage of patients undergoing PCI remained the same and the percentage of patients undergoing procedures with a radial approach also remained the same. The number of stents and vessels intervened on per interventional procedure did not decrease.

The major adverse effects of radiation can be thought of as those that are deterministic or stochastic (3). Deterministic effects are those that have a predictable dose-related increase in severity of effects above a certain threshold. Skin damage

Table 2. Baseline Demographics for the Angiograms and PCI Pre-RRP and Post-RRP

	Angiograms (n = 354)			PCI (n = 251)		
	Pre-RRP (n = 180)	Post-RRP (n = 174)	p Value	Pre-RRP (n = 129)	Post-RRP (n = 122)	p Value
Age, yrs	66 \pm 13	67 \pm 12	0.5552	67 \pm 12	65 \pm 12	0.1387
Male	94 (53)	115 (66)	0.0095	88 (69)	90 (74)	0.3809
Weight, kg	83.8 \pm 18.3	86.1 \pm 26.2	0.3409	84.2 \pm 19.5	87.3 \pm 18.9	0.2110
BMI, kg/m ²	29.6 \pm 5.7	29.7 \pm 7.4	0.9015	28.8 \pm 6.4	29.9 \pm 6.0	0.1676
Radial approach	96 (53)	87 (50)	0.5304	62 (48)	70 (58)	0.1396
Fluoroscopy time, min	4.96 \pm 0.37	5.54 \pm 0.47	0.283	13.29 \pm 0.90	13.66 \pm 1.27	0.2466
Mean cine runs	9.6 \pm 0.2	10.5 \pm 0.3	0.0218	25.6 \pm 0.9	28.7 \pm 1.2	0.0694

Values are mean \pm SD, mean \pm SE, or n (%). Age, weight, BMI for those undergoing diagnostic angiograms alone and PCI alone are expressed as mean \pm SD. Male, age, and PCI are expressed as percentages of total. Fluoroscopy time and mean cine runs are expressed as mean \pm SE.

Abbreviations as in Table 1.

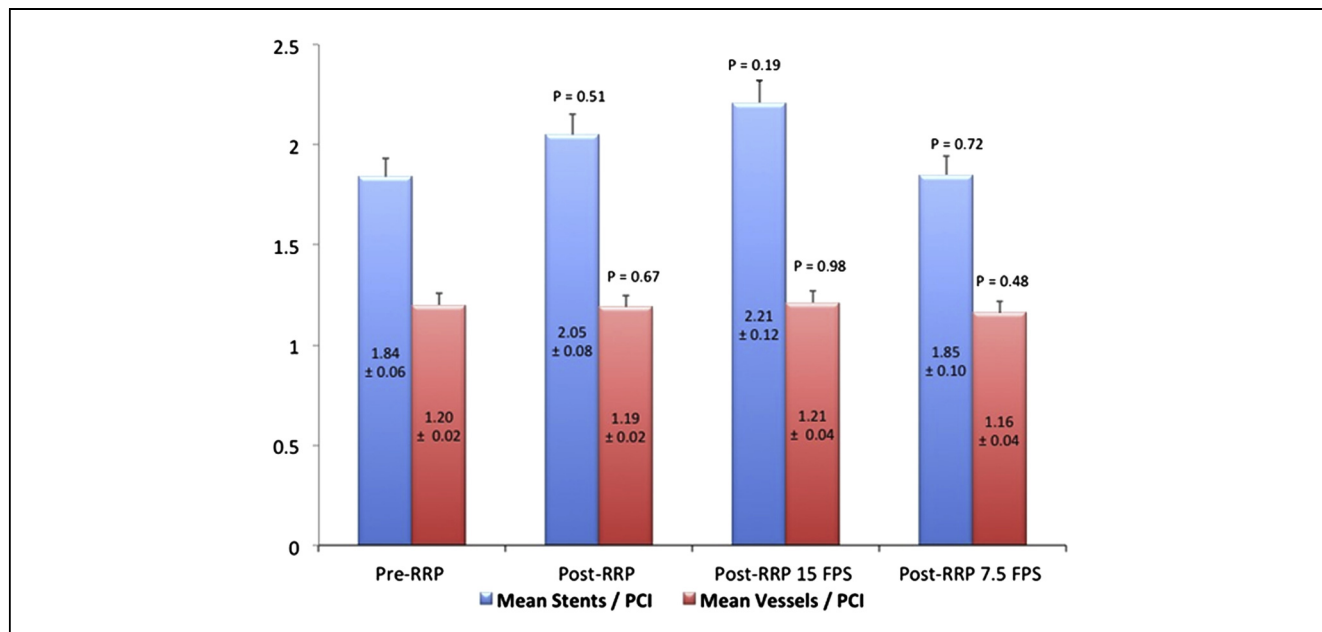


Figure 4. Cardiac Catheterization Laboratory Throughput: Mean Number of Stents and Vessels Intervened Upon

Mean number of stents and mean number of vessels intervened upon per PCI procedure pre- and post-RRP implementation as well as per the 7.5 and 15 FPS subgroups. Results are expressed as mean ± SE. The p values are compared with pre-RRP values. Abbreviations as in Figure 2.

is the most common deterministic effect of radiation exposure (4). A skin dose as low as 2 Gy has been associated with transient erythema and doses >10 to 15 Gy have been associated with skin changes ranging from telangiectasia to skin necrosis (5). Stochastic effects of radiation are inherently probabilistic effects for which there is no threshold. The most well-studied stochastic effects are increased risk of neoplasm and increased risk of teratogenicity (6). Data from atom bomb survivors suggest that an absorbed dose of 100 mGy has a detectable increase in cancer risk (7). Furthermore, female patients who were

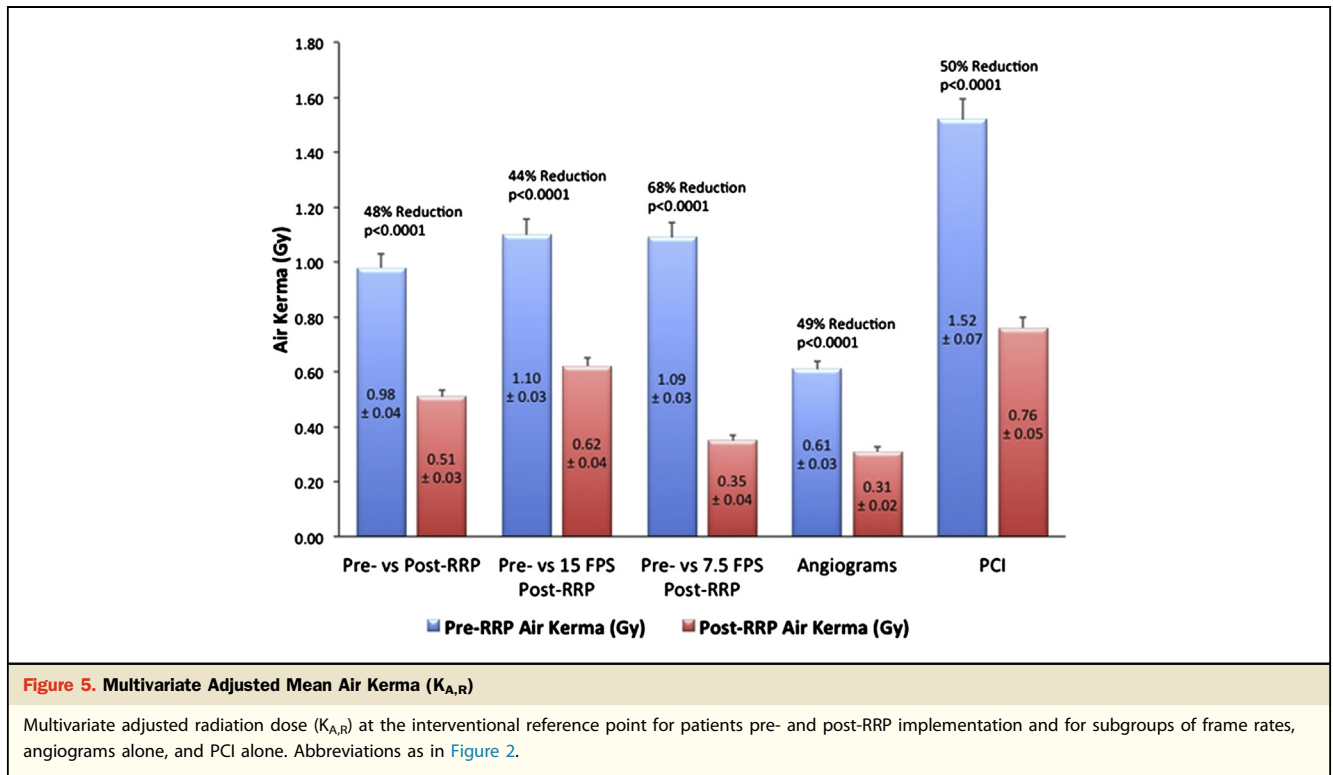
exposed to fluoroscopy to assess iatrogenically created pneumothoraxes for the treatment of tuberculosis were at higher risk to develop further malignancy (7,8).

The 2 major means of determining radiation dose are the interventional reference point also known as the air kerma ($K_{A,R}$) and dose area product (1). The interventional reference point is a point 15 cm away from the isocenter of the radiation beam. This is the most direct measure of the skin dose or the deterministic effects of radiation. The other measure is the dose area product. This is the air kerma multiplied by the cross-sectional area of the area irradiated

Table 3. Univariate Predictors of Increased Radiation Dose at the Interventional Reference Point (Air Kerma, $K_{A,R}$)

	All Studies (n = 605)		Angiograms (n = 354)		PCI (n = 251)	
	Beta Coefficient ± SE	p Value	Beta Coefficient ± SE	p Value	Beta Coefficient ± SE	p Value
Age, yrs	-0.0001 ± 0.0026	0.9809	-0.0001 ± 0.0018	0.9727	0.0009 ± 0.0048	0.8467
Male	0.2814 ± 0.0638	<0.0001	0.1433 ± 0.0452	0.0016	0.2739 ± 0.1265	0.0314
BMI, kg/m ²	0.0257 ± 0.0048	<0.0001	0.0176 ± 0.0033	<0.0001	0.0417 ± 0.0090	<0.0001
Radial	0.1280 ± 0.0624	0.0408	-0.0160 ± 0.0450	0.7226	0.3177 ± 0.1150	0.0062
PCI, yes/no	0.7437 ± 0.0558	<0.0001	—	—	—	—
Stents, n	—	—	—	—	0.2412 ± 0.0456	<0.0001
Vessels, n	—	—	—	—	0.3601 ± 0.1274	0.0051
Fluoroscopy time, min	0.0545 ± 0.0029	<0.0001	0.0336 ± 0.0038	<0.0001	0.0486 ± 0.0052	<0.0001
Cine runs	0.0407 ± 0.0021	<0.0001	0.0412 ± 0.0057	<0.0001	0.0372 ± 0.0042	<0.0001
Frame rate, 7.5 FPS	-0.5352 ± 0.0717	<0.0001	-0.3409 ± 0.0502	<0.0001	-0.7914 ± 0.1317	<0.0001
RRP	-0.5022 ± 0.0592	<0.0001	-0.3253 ± 0.0414	<0.0001	-0.7393 ± 0.1068	<0.0001

Abbreviations as in Table 1.



and represents a measure of the stochastic effects of radiation. Our study used the $K_{A,R}$ as the primary endpoint. This value is reported in most modern systems, and its value is included in catheterization reports from our laboratory.

The physician responsibilities to patients with regard to radiation safety are based on the “as low as reasonably achievable” principle (9). It is understood that ionizing radiation makes invasive diagnostics possible. However, the principle states that: 1) there is no safe dose of radiation; 2) the smaller the dose, the lower the risk; and 3) incremental doses have incremental risks. Understanding this, there are several general measures that may be taken to reduce radiation exposure that were not addressed in this study but are essential to use medical radiation safely. These are listed in the 2004 American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society/Society for Cardiac Angiography and Interventions Fluoroscopy Clinical Competence Statement: Minimize beam on time (both cine and fluoroscopy) (1), use beam collimation, minimize magnification, optimize patient and beam source and image intensifier distance, and vary the entry site of radiation. This study addresses several other points that the competence statement deals with. In this study, we used modern fluoroscopy machines that recorded the radiation dose, and the radiation dose was included in the angiographic report. This allowed operators to be aware of total dose. We tested a RRP system, ECO, that had a

sophisticated dose reduction feature. This is illustrated in Figure 1. It involved finely calibrating the dose to the patient height and weight as well as reducing the dose rate both at fluoroscopy and during cine. Increased collimation is also employed to limit beam size. Automatic dose settings were changed from normal to low. Finally, at the operator’s discretion, there was an option for reduced frame rate at 7.5 FPS as compared to traditional 15 FPS.

Study limitations. The major limitation of this research was its retrospective nature. However, it should be noted that the control period was chosen immediately prior to implementation to reduce any chances that other factors related to practice pattern would change the results. It should be noted that there were no changes to the catheterization laboratory personnel during the time of the study. The single lab and single institution design of this study mandates further multicenter validation of these results. There have been other groups who have employed similar dose reduction technologies (10,11).

As noted in this study, there was a nonstatistically significant trend toward increased numbers of cine runs. Possible explanations for this include increased operator laxity with minimizing cine runs due to the lower air kerma displayed on the monitor. Another possible explanation is that reduced image quality necessitated more cine runs. As a slight increase in the number of stents was noted in this study, a further prospective study may be needed to investigate whether there may have been more stent complications including stent edge

dissections due to lower image quality necessitating a 2-stent technique. Our study did not address this question, and this should be explored in future studies.

Conclusions

In this study of patients who underwent coronary angiography at a single catheterization laboratory before and after implementation of an RRP, we report an adjusted $K_{A,R}$ reduction of 48%, and a 68% adjusted $K_{A,R}$ reduction when a reduced frame rate was employed. We also report there was no reduction in the throughput of the laboratory as measured by the number of PCI cases, number of stents, or number of vessels intervened upon per intervention case. There was however a nonstatistically significant trend toward more cine runs once RRP was implemented. This significant radiation reduction using a novel proprietary algorithm needs strong consideration among interventional cardiology practice.

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