Effect of Reduction of the Pulse Rates of Fluoroscopy and CINE-Acquisition on X-Ray Dose and Angiographic Image Quality During Invasive Cardiovascular Procedures

Christopher T. Pyne, MD; Gautam Gadey, MD; Cathy Jeon, MD; Thomas Piemonte, MD; Sergio Waxman, MD; Frederic Resnic, MD, MSc

Background—Reducing digital pulse rates (PR) are known to reduce total energy during invasive cardiovascular procedures, which likely has benefits for patients and staff. Physicians may be reluctant to reduce these parameters because they fear a decline in image quality that could affect procedural outcomes. We sought to assess the effect of default rates of fluoroscopy (Fluoro) and CINE-acquisition (CINE) on total x-ray dose and image quality during invasive cardiovascular procedures.

Methods and Results—We retrospectively reviewed procedures done with 2 default PRs: a standard dose cohort (PR, 15 for Fluoro and CINE), and a reduced dose cohort (PR, 10 for Fluoro and CINE). Total x-ray dose, Fluoro time, and contrast use were compared between groups. A blinded angiographic image quality assessment was then performed using an objective 10-point angiographic quality score. There were no significant differences between cohorts for fluoroscopy time or contrast use. The reduced dose cohort has a significant reduction in mean total x-ray dose (PR 15, 1763.1 mGy; PR 10, 1179.1 mGy; P<0.0001). When adjusted for potential confounders, a 38% reduction in total x-ray dose was identified (P<0.0001). There was no difference in adjusted angiographic quality score between the cohorts (PR 15, 7.90; PR 10, 8.00; P=0.67), indicating no decline in image quality with PR reduction.

Conclusions—Reducing default PRs during invasive cardiovascular procedures yields large and significant reductions in total x-ray energy with no decline in angiographic image quality. (Circ Cardiovasc Interv. 2014;7:00-00.)

Key Words: angiography • fluoroscopy • image quality enhancement • x-rays
quality, a blinded angiographic quality review was performed, as described below. The study was approved by the institutional review board at Lahey Clinic Medical Center.

**Angiographic Image Quality Assessment**

To determine the effect, if any, of the reduction in CINE pulse rate on angiographic image quality, we designed a cohort study, based on review of angiographic images by board certified interventional cardiologists who were blinded to the date of the procedures. The cohort study used a 10-point scale, in which a score of 10 represented ideal image quality, judged by the operator to have optimal resolution, image contrast, clarity of cardiac motion, and tertiary branch visibility; whereas a score of 1 represented an uninterpretable angiogram. The recorded score represents the aggregate for the entire study; individual runs were not graded separately. The study was designed as a noninferiority study with 80% power to exclude a 10% reduction in measured angiographic quality score in the reduced CINE rate cohort. On the basis of preliminary exploration of angiographic quality score distribution, we calculated a sample size of 48 cases in each cohort would be necessary to establish noninferiority at a type I error level of 5%. To account for incomplete data, we conservatively increased the sample size requirement by 10%, and randomly selected 53 cases per cohort in the final study group.

Therefore, 53 patients were randomly selected from 2011 (standard CINE) and 53 patients were randomly selected from 2012 (reduced CINE), balancing the groups for clinical variables, including sex, age, acuity of clinical presentation, body mass index, renal function, and history of prior coronary artery bypass graft surgery. The cohorts were then balanced by procedure room and whether the procedure was a diagnostic or interventional procedure. Balance across these 2 covariates was achieved by randomly replacing patients in the reduced CINE cohort until the proportions of cases with these features were equal to the proportion in the standard CINE cohort.

Five experienced board-certified interventional cardiologist reviewers, with minimum experience of 5 years since completing interventional cardiology fellowship training, rated 18 randomly selected patients in the combined cohort of 106 cases. Two cases in the standard rate cohort were fluoroscopy-only procedures and, therefore, had no CINE images to review. This brought the reduced dose cohort to 51 patients for the purpose of angiographic image assessment. As stated, the reviewers were blinded to the procedure date and, therefore, also the CINE pulse rate of the angiographic study. The image assessments were done using the Philips Xcelera cardiovascular image review system (Best, the Netherlands). In addition, to adjust for any interobserver variation, each participating interventional cardiologist reviewed 5 additional cases, common to all reviewers, and all reviewers’ quality scores were recalibrated by adjusting for difference from the median scores of the commonly reviewed cases.

**Catheterization and X-Ray Techniques**

Coronary angiography and interventional procedure procedures in both the standard and the reduced dose cohorts were performed in the usual fashion. Lahey Clinic is a tertiary teaching hospital with a categorical and interventional fellowship program. Therefore, most procedures are performed with an attending cardiologist and 1 fellowship trainee. There are no standard protocols in the laboratory for access site, image acquisition angles, number of CINE, image centering, or other technical procedure details, and these are left to operator discretion to optimize image use for each individual patient. Cases were performed in 2 different angiographic suites. Both rooms consisted of the AXIOM Artis angiography system and Sensix software package (Siemens Corporation, Munich, Germany). These systems display the real-time x-ray dose during procedures in milligray. The manufacturer defines the displayed dose as the cumulative patient dose and corresponds to the dose at a reference point 15 cm toward the x-ray tube from the iso-center of the field. This reference point allows the assumption that the value represents the cumulative skin dose for the patient.

The pulse rates for fluoroscopy and CINE are set by the technologist at a default rate that can be adjusted by the operating physician during
the procedure at their discretion. In 2011, that default rate was set at 15 pulses per second and was adjusted down to 10 pulses per second early in 2012. The quantitative dose per pulse is not fixed, but instead it is autoregulated by the x-ray equipment to maintain image quality. In our laboratory, reducing pulse rates does not substantially change the quantitative energy per pulse although small changes in current or pulse width may be made by the equipment to maintain the image. There was no change in image filtering between the cohorts. The change in the default pulse rates for both fluoroscopy and CINE was known to all operators in the laboratory. Although operators have the ability to modify the preset pulse rates real-time during procedures, this is done only in rare circumstances, so that the default settings are by far the most common x-ray parameters used throughout the procedures analyzed. Therefore, for practical purposes, the only significant difference in acquisition parameters between the standard and the reduced dose cohorts was the default pulse rates. In addition, operator protection did not differ between study periods. All operators wore standard 2-piece lead apron and thyroid shield. Ceiling and table mounted lead shielding did not differ between cohorts, and most radial cases had enhanced operator shielding consisting of additional pelvic drapes.13

Primary End Points

The primary end point of the radiation exposure study is the adjusted mean total x-ray dose (also commonly referred to as the air kerma) expressed in milligray. Secondary end points of fluoroscopy time and contrast dose are also reported. In addition, we sought to assess the effect on pulse rate reduction on the percentage of patients whose procedures were performed with total x-ray energy of <2 Gy. This number was chosen because it is a generally accepted skin dose threshold for deterministic injury for patients and prompts patient notification of potential x-ray harm in our laboratory. The primary end point of the angiographic quality sub study is the difference in the mean angiographic quality scores, as assigned on a 1 to 10 scale as noted above, between the 2 matched study cohorts.

Statistical Analysis

Categorical values are presented as numbers and percentages and were assessed using the χ² test. Continuous variables as mean±SD and were analyzed using the Student t test. Because the distribution of the fluoroscopy and x-ray dose outcomes was skewed, a log transformation was done to normalize the distributions. To ease in data interpretation, the data were re-exponentiated for presentation. Univariate associations of clinical and demographic variables with the outcome of total x-ray dose were calculated using the nonparametric Spearman rank test. A multivariable regression model was developed using the Lasso method to select the optimal covariates based on choosing the model with the lowest Akaike information criteria as a measure of model fit in the log transformed linear regression model, assessing all covariates with a univariate association with P≤0.10. The model was then used to adjust for patient and procedural variables that would likely influence total x-ray dose. Statistical analysis was performed with SAS system for Windows version 9.3 (SAS Institute Inc, Cary, NC).

Results

There were 1015 cases examined for the outcome of total x-ray dose. A total of 524 in the standard dose cohort (default pulse rate set to 15 FPS for both fluoroscopy and CINE) and 491 in the reduced dose cohort (default pulse rate set to 10 FPS for both fluoroscopy and CINE). There were no significant differences between the groups with respect to patient demographics (Table 1). There were small but significant differences in the proportion of patients undergoing diagnostic procedures (standard dose diagnostic catheterization, 91.8%; reduced dose diagnostic catheterization, 95.7%; P=0.01) and a history of percutaneous coronary intervention (standard dose history of percutaneous coronary intervention, 32.1%; reduced dose history of percutaneous coronary intervention, 25.5%; P=0.02) between the cohorts. There was no difference in percentage of patients with femoral or radial access between groups. (standard dose 62.2% radial; reduced dose 61.3% radial; P=0.77). Postprocedural total x-ray dose, fluoroscopy times, and contrast volume used are presented in Table 2. There was a 33% reduction in unadjusted mean x-ray dose in the reduced dose group (cohort 2) when compared with the standard dose group (standard dose, 1763±1388 mGy; reduced dose, 1179±1147 mGy; P<0.0001). There was also a 47.9% reduction in the reduced dose cohort of patients with total energy exposures >2 Gy (standard dose cohort, 31.7%; reduced dose cohort, 16.5%; P<0.0001). When adjusted for potentially confounding patient and procedural variables, including patient sex, body mass index, history of coronary artery bypass graft hypertension, hyperlipidemia, procedure type (diagnostic or coronary intervention), and patient weight, the reduction in total x-ray dose remained significant with a 38% reduction in total dose between the standard dose group and the reduced dose group (P<0.0001). There were no differences between groups with respect to fluoroscopy time (standard dose, 13.2±12.3 minutes; reduced dose, 12.8±12 minutes; P=0.59) or contrast dose (standard dose, 147.4±88.5 minutes; reduced dose, 155.8±98.1 minutes; P=0.15). The distributions of the total x-ray dose per case are represented in the Figure and reveal a marked shift in cases toward lower energy levels.

There were 104 cases (10.2% of study population) examined for the outcome of angiographic quality assessment. There were no significant differences between the groups for patient variables, fluoroscopy times, or access site (Table 3). However, total x-ray dose was reduced by 33.7% in the reduced dose cohort studied when compared with the standard dose group (standard dose, 1451±1215.7 mGy versus reduced dose, 962.1±846.6 mGy; P=0.02), which mimics the effect of the reduced dose strategy in the overall study cohort. Results of the angiographic quality score (AQS) are presented in Table 4. There were no significant differences between the groups for unadjusted angiographic quality scores (standard dose AQS, 7.98±0.144; reduced dose AQS, 8.06±0.146; P=0.64), indicating that the reduced dose groups had no decline in image quality when compared with the standard dose group. When the angiographic quality scores were adjusted for potential interobserver variability in image quality assessment, the noninferiority of the reduced dose when compared with the standard dose group was maintained (standard dose adjusted AQS, 7.90±0.146; reduced dose adjusted AQS, 8.00±0.152; P=0.67).

Discussion

This retrospective study demonstrates a large and significant reduction in adjusted total x-ray energy when the pulse rates for both fluoroscopy and CINE were reduced from 15 to 10 per second. Reducing pulse rates did not increase fluoroscopy time or contrast use. Most importantly, there was no reduction in image quality as assessed by experienced interventional cardiologists. Therefore, patients, operating physicians, and staff radiation exposures were significantly reduced by simple methods with no noticeable penalty of inferior image quality or prolonged fluoroscopy time.

Reducing total energy levels during cardiac procedures likely has significant benefits for both patients and the physicians.
performed the procedures. Deterministic injury on patients has been shown to be directly related to the total energy dose. Transient skin erythema can be seen at a threshold as low as 2 Gy depending on the x-ray beam configuration. Permanent skin changes can be seen at doses exceeding 5 Gy, particularly in cases where the x-ray beam position remains fixed. Given the 2 Gy threshold for potential skin entry injury, the results of this study indicate a potential benefit to patients from the reduced default DPF, with a \( \approx 50\% \) reduction in cases whose cumulative skin dose exceeded 2 Gy in the reduced pulse rate group. Equally important are concerns about cumulative career doses for operating physicians and potential stochastic effects. Venneri et al.\(^3\) reported a non-negligible risk of fatal or nonfatal cancers attributable to nonionizing radiation for the highest volume proceduralists. Although operator exposure was not directly measured in our data set, there is an a priori probability that operator exposure will be reduced to a similar magnitude. A mean 38% reduction in total energy per case will likely translate into significant reduction in lifetime cumulative radiation doses for operating physicians and circulating staff.

Despite improvements in x-ray equipment during the past several years, operator exposure remains significant, and increased procedural complexity may offset improvements in radiation technology. Following the principles of As Low as Reasonably Achievable and maintaining careful attention toward limiting fluoroscopic time will limit patient and physician exposure, as much as 80% of x-ray time is determined by patient characteristics and procedural complexity that cannot be modified by the operator. Technical and anatomic factors during procedures likely have the largest effect on an individual case x-ray exposure. As the principal determinant of occupational radiation exposure for operators is patient scatter, reducing total energy to patients directly affects physician and staff exposures as well. Clearly, efforts to reduce radiation exposure for both patient and staff need to be a critical part of every catheterization laboratory’s quality improvement mission. However, given that patient and procedural characteristics limit the ability of operators to decrease fluoroscopy times markedly, techniques that lower x-ray energy per period of fluoroscopy and CINE represent a significant opportunity to reduce patient and staff radiation exposure further.

Both the Society for Cardiovascular Angiography and Interventions and the American College of Cardiology/American Heart Association have published position papers on reducing patient and physician exposure during cardiac procedures. These include careful patient selection, careful

Table 1. Comparison of Patient and Procedural Characteristics Between the Standard Dose Cohort (DPF and CINE of 15 FPS) vs the Reduced Dose Cohort (DPF and CINE of 10 FPS)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Reduced Dose (n=491)</th>
<th>Standard Dose (n=524)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (% men)</td>
<td>70.5</td>
<td>70.0</td>
<td>0.88</td>
</tr>
<tr>
<td>Age, y</td>
<td>65.2±12.6</td>
<td>65.7±11.7</td>
<td>0.52</td>
</tr>
<tr>
<td>Height, cm</td>
<td>171.4±10.0</td>
<td>171.6±9.8</td>
<td>0.74</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>86.8±19.7</td>
<td>86.4±19.2</td>
<td>0.74</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>29.5±5.7</td>
<td>29.3±5.7</td>
<td>0.62</td>
</tr>
<tr>
<td><strong>Medical history, %</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco use</td>
<td>17.5%</td>
<td>18.5</td>
<td>0.68</td>
</tr>
<tr>
<td>Hypertension</td>
<td>78.4</td>
<td>81.1</td>
<td>0.29</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>82.1</td>
<td>81.7</td>
<td>0.87</td>
</tr>
<tr>
<td>Previous MI</td>
<td>36.7</td>
<td>35.9</td>
<td>0.80</td>
</tr>
<tr>
<td>History of CHF</td>
<td>13.2</td>
<td>16.0</td>
<td>0.21</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>25.5</td>
<td>32.1</td>
<td>0.02*</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>11.8</td>
<td>15.3</td>
<td>0.11</td>
</tr>
<tr>
<td>Dialysis</td>
<td>4.7</td>
<td>3.2</td>
<td>0.24</td>
</tr>
<tr>
<td>Cerebral vascular disease</td>
<td>10.0</td>
<td>11.3</td>
<td>0.51</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>11.4</td>
<td>13.7</td>
<td>0.26</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>13.8</td>
<td>17.2</td>
<td>0.14</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>28.9</td>
<td>33.4</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Procedure, %</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>44.8</td>
<td>47.5</td>
<td>0.39</td>
</tr>
<tr>
<td>Diagnostic catheterization</td>
<td>95.7</td>
<td>91.8</td>
<td>0.01*</td>
</tr>
<tr>
<td>Access site (% radial)</td>
<td>61.3</td>
<td>62.2</td>
<td>0.77</td>
</tr>
</tbody>
</table>

BMI indicates body mass index; CABG, coronary artery bypass graft surgery; CHF, congestive heart failure; DPF, digital pulse fluoroscopy; MI, myocardial infarction; and PCI, percutaneous coronary intervention.

\*P values <0.05.

Table 2. Unadjusted Outcome in the Total X-Ray Dose Analysis

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Reduced Dose (n=491)</th>
<th>Standard Dose (n=524)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy time, min</td>
<td>12.8±12.0</td>
<td>13.2±12.3</td>
<td>0.59</td>
</tr>
<tr>
<td>Contrast volume, mL</td>
<td>156.1±98.0</td>
<td>147.7±88.4</td>
<td>0.15</td>
</tr>
<tr>
<td>Total dose, mGy</td>
<td>1179.1±1147.0</td>
<td>1763.1±1388.0</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Total dose &gt;2 Gy, %</td>
<td>16.5%</td>
<td>31.7%</td>
<td>&lt;0.0001*</td>
</tr>
</tbody>
</table>

Dose >2 Gy refers to percentage of cases whose recorded total x-ray dose exceeded 2 Gy. Total dose represents the mean total x-ray dose.

\*P values <0.05.

Figure. Distribution of x-ray doses in the standard and reduced dose cohorts (n=patient number, all x-ray values are in milligray).
In our experience, however, no such image quality concerns were identified by our interventional cardiologists, all of whom were aware of the reductions in the preset pulse rates. This prompted the design of the noninferiority angiographic quality substudy. As is described in the Methods section of this article, particular attention was paid to assessment of fine angiographic points, such as tertiary branch visualization, in addition to more traditional measures of image quality, such as resolution and contrast. Careful attention was paid to factors that could affect image quality, such as patient size, access site, and percentage of patients undergoing interventions. When adjusted for all patient and procedural features, the noninferiority of image quality with reduced dose CINE was maintained, reassuring physicians that reductions in case total energy do not come at the expense of reduced image quality.

Finally, it should be noted that a significant proportion of procedures in both cohorts was performed via the transradial route. As our institution has been performing transradial procedures as the preferred access site for >5 years, and all attending physicians are experienced with the technique, it is unlikely that there was any effect of a learning curve between the cohorts. Of course, the trainees would be affected by the increase fluoroscopy times associated with learning the technique, but these effects should be generally balanced in the 2 cohorts as the periods selected as described above.

As with any retrospective analysis, this study has the potential for unmeasured confounding although every effort was made to adjust for potential confounders of total radiation dose and angiographic quality. In addition, there were limited differences in the baseline characteristics of the patient populations during 2 periods studied. Within the angiographic quality substudy, blinding of the image reviewer as to the dose exposure study period and original physician performing the study was intended to minimize observational bias in the assessment of image quality, recognizing the intrinsic limitations of this strategy. Although the angiographic quality study did not analyze quantitative image characteristics, such as average image contrast and edge sharpness, the use of qualitative assessment of overall image quality is consistent with the clinical use of CINE images in routine practice.

### Conclusions

Reductions in default pulse rates for both fluoroscopy and CINE are easily implemented on modern cardiac angiographic systems and can result in significant reductions in mean total x-ray energy delivered during invasive cardiac procedures. Reductions in pulse rates for fluoroscopy and CINE did not lead to a perceptible decline in angiographic image quality or an increase in contrast use or overall fluoroscopy time. Individual laboratories should assess the effect on pulse rate reductions on total energy with their x-ray equipment. Reductions in default pulse rates for both fluoroscopy and CINE should be considered, along with traditional As Low as Reasonably Achievable recommendations, to reduce radiation exposure in patients, operating physicians, and circulating staff.
Acknowledgments
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Disclosures
None.

References
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