## Clinical Investigation

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# Effective Reduction of Radiation Exposure during Cardiac Catheterization

Exposure to ionizing radiation during cardiac catheterization can have harmful consequences for patients and for the medical staff involved in the procedures. Minimizing radiation doses during the procedures is essential. We investigated whether fine-tuning the radiation protocol reduces radiation doses in the cardiac catheterization laboratory.

In January 2016, we implemented a new protocol with reduced radiation doses in the Hospital de Jerez catheterization laboratory. We analyzed 170 consecutive coronary interventional procedures (85 of which were performed after the new protocol was implemented) and the personal dosimeters of the interventional cardiologists who performed the procedures.

Overall, the low-radiation protocol reduced air kerma (dose of radiation) by 44.9% (95% Cl, 18.4%–70.8%; P=0.001). The dose-area product decreased by 61% (95% Cl, 30.2%–90.1%; P <0.001) during percutaneous coronary interventions. We also found that the annual deep (79%, P=0.026) and shallow (62.2%, P=0.035) radiation doses to which primary operators were exposed decreased significantly under the low-radiation protocol. These dose reductions were achieved without increasing the volume of contrast media, fluoroscopy time, or rates of procedural complications, and without reducing the productivity of the laboratory.

Optimizing the radiation safety protocol effectively reduced radiation exposure in patients and operators during cardiac catheterization procedures. (Tex Heart Inst J 2019;46(3):167-71)

xposure to ionizing radiation during cardiac catheterization procedures is a major concern for patients and for the clinicians who perform the procedures. Radiation exposure can result in long-term health effects, including skin and eye damage, and may cause certain forms of cancer by interacting with and altering cellular DNA.<sup>1-5</sup>

The deleterious effects of ionizing radiation on human tissue can be categorized into 2 types: deterministic and stochastic.<sup>6,7</sup> Deterministic effects are characterized by a predictable dose-related increase in severity, which can be evaluated by means of air kerma (kinetic energy released per unit mass, AK), or radiation dose, measurements.<sup>8-11</sup> Stochastic effects follow a linear, no-threshold risk model, in which the risk of damage to the irradiated tissue increases linearly with the amount of exposure. Stochastic effects are measured by dose-area product (DAP).<sup>7,8</sup>

Interventional cardiologists experience the highest annual radiation exposure of all health professionals.<sup>3</sup> The excess lifetime cancer risk of an interventional cardiologist is 1 in 100.<sup>9</sup> In recent years, radiation exposure during cardiac catheterization procedures has attracted increasing attention among interventional cardiologists, who have a strong interest in reducing radiation doses during such procedures.<sup>2,5,7,10</sup>

Our objective was to investigate whether fine-tuning radiation safety protocols could reduce radiation doses without compromising the effectiveness of catheterization procedures in patients.

## **Patients and Methods**

In early January 2016, the Innova<sup>®</sup> 2000 (GE Medical Systems) digital imaging system in the cardiac catheterization laboratory at Hospital de Jerez was upgraded, and a new low-radiation protocol (LRP) was implemented.

As part of the upgrade, the Innova central touchscreen and in-room stenosis analysis were introduced. These tools provide simple access to key features throughout patient The LRP consisted of reducing frame rates from 15 to 7.5 frames/sec and switching the default fluoroscopy dose setting from normal to low. In addition, the catheterization laboratory staff were advised to reduce radiation exposure by using the LRP as much as possible.

We analyzed 170 consecutive catheterization procedures, including percutaneous coronary intervention (PCI) procedures and diagnostic coronary angiographic procedures. Half of the procedures (n=85) were performed before and half (n=85) were performed after implementation of the LRP.

The patients' radiation dose reports included DAP, AK, total fluoroscopy time, and total procedural time. We also collected baseline patient and procedural characteristics. Subgroup analyses were performed for patients undergoing only diagnostic angiography as well as for those undergoing PCI.

We also studied radiation exposure in the operators. There were no changes in operators or seasonal differences during the investigation period. Annual radiation exposure data were collected from the wrist and pocket dosimeters that operators used from 2012 through 2016. The operators typically used 0.35-mm lead aprons (except for operator 2, who used a 0.5-mm lead apron), thyroid collars, and protective eyewear with a lead equivalence of 0.5 mm.

This study was conducted in compliance with the guidelines for human subjects research and was approved by an institutional review committee. All patients provided written informed consent.

#### **Statistical Analysis**

The Kolmogorov-Smirnov test was used to examine the normality of data distribution. Continuous variables, expressed as mean  $\pm$  SD, were compared by using the *t* test or the Mann-Whitney U test, as appropriate. Categorical variables, expressed as number and percentage, were compared by using  $\chi^2$  analysis or the Fisher exact test, as appropriate. Analysis of variance was used for multiple-group comparison. A *P* value <0.05 was considered statistically significant. SPSS version 22.0 (SPSS, an IBM company) was used for all statistical analyses.

Of note, AK levels in diagnostic procedures are substantially lower than those in PCI procedures (which are longer and more complex). Accordingly, the overall radiation dose (PCI plus diagnosis) was obtained not by adding PCI procedures plus diagnostic procedures, but rather by calculating AK from all procedures (PCI and diagnostic); therefore, the value is lower than that of the PCI procedures but higher than that of the diagnostic procedures.

#### Results

We retrospectively collected data for 170 consecutive patients who underwent cardiac catheterization at our institution from November 2015 through February 2016. Of those patients, 110 (65%) underwent PCI procedures.

The original radiation protocol (ORP) was used in 85 patients (56/85, 65.9% PCI procedures). The other 85 patients (54/85, 63.5% PCI procedures) underwent catheterization after the new LRP was implemented in January 2016.

Table I shows the clinical and procedural characteristics of the study population. Radial artery access was used to perform most of the procedures in both groups. There were no significant differences in patient characteristics, complexity of the lesions, or major complication rates between the 2 groups.

Table II compares the radiation doses between the 2 patient groups. We noted no statistically significant differences in the average volume of contrast media used during the procedures (Table I) or in fluoroscopy time (Table II).

Air kerma was significantly reduced during the PCI procedures performed in the LRP group; however, no

TABLE I. Clinical and Procedural Characteristics of the
Patients

Variable	<b>ORP</b> (n=85)	<b>LRP</b> (n=85)	P Value				
Age (yr)	66.9 ± 11	64.2 ± 13	0.16				
Weight (kg)	$80.7\pm14$	81.8 ± 14	0.6				
Body mass index (kg/m²)	$29.3\pm5.3$	$29.7\pm4.7$	0.6				
Female	23 (27)	23 (27)	>0.99				
Radial approach	73 (86)	74 (87)	0.8				
PCI	56 (65.9)	54 (63.5)	0.7				
Contrast volume (mL)	$161.3\pm121$	$152\pm115$	0.4				
PCI procedures (n=110, 65%)							
Multivessel	24 (28)	24 (28)	>0.99				
Vessels treated/patient	$1.79\pm0.7$	$1.71\pm0.8$	0.5				
Left main	2 (2.3)	3 (3.5)	0.6				
Chronic total occlusion	4 (4.7)	3 (3.5)	0.6				
Rotational atherectomy	0	1 (1.1)	0.3				
Major complications	0	0	>0.99				
Contrast volume (mL)	$203\pm128$	$190\pm126$	0.5				

LRP = low-radiation protocol; ORP = original radiation protocol; PCI = percutaneous coronary intervention

Data are expressed as mean  $\pm$  SD or as number and percentage. *P*<0.05 was considered statistically significant.

**TABLE II.** Comparison of Patients' Radiation According to Protocol

Variable	ORP	LRP	<b>P</b> Value <0.001	
<b>Total procedures</b> (N=170)	85 (50)	85 (50)		
AK (mGy)	$687\pm748$	$379\pm379$	0.001	
AK/Fluoroscopy time (mGy/min)	$54.3\pm22$	$36.9\pm22$	<0.001	
AK/Contrast volume (mGy/mL)	$3.9\pm2.4$	2.4 ± 1.3	<0.001	
Procedural time (min)	$37\pm32$	38±33	0.8	
Fluoroscopy time (min)	12.9±13	13.5±14	0.7	
<b>PCI</b> (n=110, 65%)	56 (51)	54 (49)	<0.001	
AK (mGy)	$922\pm823$	$476\pm433$	0.001	
Dose-area product (Gy•cm²)	$92\pm78$	$36\pm35$	<0.001	
Diagnostic (n=60, 35%)	29 (48)	31 (51)	<0.001	
AK (mGy)	231 ± 145	$210\pm154$	0.5	
Dose-area product (Gy•cm²)	$21\pm19$	18 ± 16	0.4	

AK = air kerma; LRP = low-radiation protocol; ORP = original radiation protocol; PCI = percutaneous coronary intervention

Data are expressed as number and percentage or as mean  $\pm$  SD. P < 0.05 was considered statistically significant.

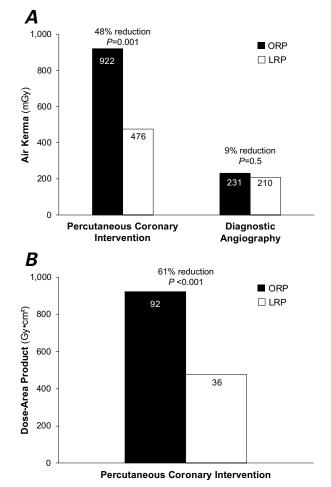
such reductions were noted during the diagnostic procedures (Fig. 1 and Table II).

Air kerma was reduced by 44.9% (95% CI, 18.4%– 70.8%; P=0.001) in the overall patient population (including PCI and diagnostic procedures) and by 48.3% (95% CI, 21.2%–75.4%; P=0.001) in the PCI group. During PCI procedures, the LRP was even more effective in reducing DAP (61% reduction; 95% CI, 30.2%– 90.1%; P <0.001).

The operators' personal dosimeters showed an average reduction of 79% in the annual deep dose for the year 2016 compared with the 2015 dose (P=0.026), and a 76.4% reduction when compared with the average dose for the years 2012 through 2015 (P=0.049). The average annual shallow dose in 2016 was also reduced by 62.2% when compared with the 2015 dose (P=0.035) and by 58% when compared with the average dose for the years 2012 through 2015 (P=0.02) (Table III).

#### Discussion

Radiation exposure during cardiac catheterization can result in substantial adverse health effects for patients and operators. The harmful effects of ionizing radiation



**Fig. 1** Compared with the original radiation protocol (ORP), the low-radiation protocol (LRP) significantly reduced the **A**) air kerma and **B**) dose-area product levels in patients who had percutaneous coronary intervention. P <0.05 was considered statistically significant.

include skin and eye damage, as well as certain forms of cancer consequent to the interaction of radiation with cellular DNA.<sup>1-5</sup> Although advances in technology and fine-tuning of radiation safety protocols over the past decades have reduced radiation doses in patients and operators,<sup>2</sup> the catheterization laboratory continues to be a significant source of radiation.<sup>7</sup>

Implementing our LRP, as well as stressing the importance of reducing radiation exposure to our operators, resulted in significant reductions in DAP and AK in our cardiac catheterization laboratory, without increasing procedural complications, fluoroscopy time, or the volume of contrast media used during the procedures. Moreover, the productivity of the laboratory was not reduced, as illustrated by the volume of PCI cases and the number of complex PCI procedures (such as management of chronic total occlusion or left main interventions) performed during the study period, as well as the number of treated vessels per patient in both groups. TABLE III. Comparison of Operators' Annual Radiation Doses According to Protocol

<b>Protocol</b> (Time Period)	Exposure Type	Average Dose per Operator* (mSv)					
		1	2	3	4	5	$Mean \pm SD$
ORP (2012–2015)	DD SD	5.75 104.75	0.55 166.8	1.45 42.7	5.3 69.3	4.35 150.45	3.48 ± 2.5 106.8 ± 52
ORP (2015)	DD SD	2.6 108.5	0.5 153.6	3.7 31.8	7.2 120	5.3 162.9	$\begin{array}{c} 3.86 \pm 2.5 \\ 118 \pm 54.5 \end{array}$
LRP (2016)	DD SD	0.1 15	80.3	0.1 18.4	0.6	2.5 64.9	$\begin{array}{c} 0.82 \pm 1.1 \\ 44.6 \pm 32.9 \end{array}$

DD = deep dose; LRP = low-radiation protocol; ORP = original radiation protocol; SD = shallow dose

\*Measured by personal dosimeters

Therefore, the LRP effectively reduced the overall radiation exposure of patients and staff during interventional cardiovascular procedures.

The magnitude of AK reduction was 48.3% for patients who underwent PCI; the LRP was even more effective in reducing DAP (61%). The reduction in radiation doses after the implementation of our LRP was similar to data reported in previous studies. Wassef and colleagues<sup>7</sup> noted a 48% reduction in AK during catheterization procedures after implementing a novel radiation-reduction protocol like ours.

By significantly decreasing DAP and AK, the LRP reduced the deterministic and stochastic effects of radiation. These reductions were evident in the personal dosimeters of the operators, in which the annual shallow dose and especially the annual deep dose were significantly reduced in the year 2016, after we implemented the LRP, compared with the previous years during which the ORP was used. The fact that the dose reductions were achieved by the same operators, who worked with both protocols, confirms that the results were operator-independent.

Although no amount of radiation can be considered safe, proper use of ionizing radiation is a necessary step in all cardiac catheterization procedures. Optimizing radiation protocols in catheterization laboratories to improve the safety of patients and medical staff should become a priority. When it comes to protecting patients from the adverse effects of radiation exposure, all health professionals should be guided by the "as low as reasonably achievable" principle of radiation safety.<sup>2,9,12</sup>

#### **Study Limitations**

Our study has several limitations. The study was limited to a single center and included a small number of patients. It should be investigated whether our findings can be replicated in larger patient cohorts. In addition, the data were acquired consecutively instead of using randomization, which would minimize variability caused by operator availability and procedural workflow changes over time. Finally, some data from the operators' dosimeters were not available.

#### Conclusions

Optimizing the radiation protocol effectively reduced the radiation exposure in patients and medical staff during cardiac catheterization procedures.

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