Effect of Physician Training on the X-Ray Dose Delivered During Coronary Angioplasty

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ABSTRACT: Objective. To assess whether physician training helps decrease the amount of radiation delivered to patients undergoing coronary angioplasty with stent placement. Background. Coronary angioplasty exposes patients to high doses of ionizing radiation, possibly related to equipment misuse or inappropriate training. Methods. Reference point air kerma ($K_a,r$) and kerma area product ($P_{KA}$) were prospectively registered during a period of 6 months in patients undergoing coronary angiography and angioplasty with stent ad hoc. All interventionals were then invited to an informative conference on appropriate use of radiation and changes in x-ray delivery settings. Data were recorded during the following 6 months and then compared for the whole group and for those who did or did not attend the conference. Results. $K_a,r$ decreased from $5.44 \pm 0.3$ Gy ($n = 106$) to $3.39 \pm 0.22$ Gy ($n = 112$); $P_{KA,0001}$ and $P_{KA}$ decreased from $365.4 \pm 21.1$ Gy·cm$^2$ to $233.7 \pm 13.1$ Gy·cm$^2$; $P_{KA,0001}$. During the first 6 months, there were no differences in radiation emitted among physicians; however, during the second half of the study, there was a $34\%$ difference in $K_a,r$ between those that attended the conference and those who did not ($2.78 \pm 0.23$ Gy vs $4.18 \pm 0.37$ Gy; $P = .002$), regardless of the fact that both groups lowered radiation emission settings. Conclusion. Changes in x-ray parameters profoundly reduce the amount of radiation delivered to patients, a situation that was more evident in those who attended an informative conference. It is important to educate cardiologists in the appropriate use of modern x-ray equipment.

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Exposure to ionizing radiation in the United States increased from 3.6 mSv/person/year in 1980 to 6.25 mSv/person/year in 2006. Almost half came from medical sources, a third from computed tomography (CT) scans and nuclear diagnostic tests, and 7% from therapeutic fluoroscopy-guided procedures.

Radiation delivered to patients during interventional endovascular procedures has been reported as high and is associated with acute deterministic deleterious skin effects and possibly a long-term increase in the risk of cancer.

Interventional cardiac procedures, either for coronary or structural diseases, have been rapidly growing over the past two decades.

Nonetheless, physicians who are not adequately trained in radiation safety and radiobiology and are not aware of the potential for injury from these procedures and the simple methods available for decreasing its incidence, perform many of these interventions. Some cases, skin doses may approach those observed in some cancer radiotherapy fractions.

Simple techniques including modifications in x-ray output, collimation, magnification, and optimal projections have been described. Some may have spectacular results in dose reduction, especially when performed by skilled physicians. Also, radiation-protection training reduces the kerma area product ($P_{KA}$) delivered to patients undergoing invasive coronary procedures. Whether physicians who do not comply with appropriate training in radiation safety and protection expose their patients to unnecessary amounts of radiation is not known. Therefore, the objective of this study was to compare radiation exposure during interventional coronary procedures, performed by cardiologists trained to reduce x-ray doses and those who were not, after modifying computerized emission radiation parameters.

Methods

Patients. All patients referred for coronary angioplasty with stent placement during a 12-month period were consecutively included in the study. There were no exclusions. The facility is a 200-bed private general hospital, located in northern Mexico, with two catheterization laboratories, performing close to 1000 endovascular diagnostic and interventional procedures, half of them cardiac.

Definitions. Air kerma (the kinetic energy released in a mass of air) is the sum of the initial kinetic energies of all the secondary electrons released by the ionizing x-ray photons per unit mass of air. Reference point air kerma ($K_a,r$) is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry during a procedure. It reflects deterministic risks. This measure is sometimes referred to as reference dose, cumulative dose, or cumulative dose at a reference point. Kerma area product ($P_{KA}$) is the integral of air kerma.

Abbreviations

DRL = diagnostic reference levels
Gy = Gray
ips = images per second
$K_{a,r}$ = reference point air kerma
$P_{KA}$ = kerma area product
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The entire x-ray beam. 14  PKA  is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. It is also known as dose-area product and can serve as an indicator of stochastic risk.13,15,16 Radiation time in this study was the sum of time in seconds when either pulsed fluoroscopy or image acquisition were activated. It is a poor indicator of radiation dose, since it lacks correlation with other dose metrics.14,15

Equipment. The angiographic unit is equipped with a flat panel-imaging detector (Innova 3100, General Electric) with an amorphous silicon photo diode array, which offers a choice of four imaging field dimensions of 30 x 30 cm, 20 x 20 cm, 16 x 16 cm, and 12 x 12 cm. In addition, the unit is capable of performing pulsed fluoroscopy at rates of 7.5, 15, and 30 images per second (ips), and acquisitions at 15 and 30 ips. Fluoroscopy detail can be set at “normal” or “low,” with entrance dose rates at the interventional reference point near 85 mGy·min⁻¹ when set at 15 ips with “normal detail” and 45 mGy·min⁻¹ when set at 15 ips with “low detail,” both below international requirements, usually <100 mGy-min⁻¹.17 This unit is also capable of recording the last fluoroscopy run when activating the “fluoro store” function. An automatic exposure control system regulates kV and mA in fluoroscopy and acquisition modes. The equipment has a flat ionization chamber PKA meter placed in front of the x-ray tube, mounted directly to the collimator (Diamantor M4 KDK), capable of measuring Kₐ,r  (in mGy) and Pₖₐ (in cGy·cm⁻²), with an accuracy of 10.5%.17

Protocol. This is a prospective, non-randomized, longitudinal, unblinded, comparative, experimental trial, where interventions included the adjustments in x-ray delivery dose and instructions to physicians. The study was divided into two periods. During the first 6 months, data were acquired with special attention to the radiation-emitted dose. At the end of this initial period, all cardiologists performing coronary angioplasties were invited to an instructional conference. The agenda included basic principles on radiobiology, deterministic and stochastic effects as well as occupational hazards of radiation. Data for Kₐ,r, Pₖₐ, and radiation time emitted were presented, giving a comparison for each individual cardiologist’s data to the mean radiation of the group and internationally accepted reference levels.

Later, adjustments to the x-ray suite default coronary program were suggested. These included a modification to the coronary “default” program to decrease the acquisition rate from 30 ips to 15 ips and the fluoroscopy rate from 15 ips to 7.5 ips, with the use of the “low fluoroscopy” detail program. Instructions on how to follow the Kₐ,r  and Pₖₐ  on the monitors, as well as keeping a minimum of magnification and use of collimator, were given. Avoiding unnecessary acquisitions such as balloon inflations and intravascular ultrasound runs were encouraged, replacing them with the “fluoro store” function. A “radiation traffic light” was installed in the catheterization laboratory to help physicians follow recommendations. It lighted green from 0 to 2 Gy of Kₐ,r  and manually switched to yellow when >2 but <5 Gy accumulated, and then to red, if >5 Gy were

Figure 1. Reference point air kerma (Kₐ,r) and kerma area product (Pₖₐ), comparing two 6-month periods, before and after training in radiation protection. Results expressed as mean ± SEM.

Figure 2. Reference point air kerma (Kₐ,r) and kerma area product (Pₖₐ) comparing two 6-month periods, before and after training in radiation protection to interventional cardiologists. The upper panel shows radiation parameters when decreasing from 15 ips fluoroscopy and 30 ips acquisition (F15/A30) to 15 ips fluoroscopy and 15 ips acquisition (F15/A15). The lower panel depicts the effects when decreasing from F15/A30 to 7.5 ips fluoroscopy and 15 ips acquisition (F7.5/A15). Results expressed as mean ± SEM.
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emitted. Procedure length was at physician’s discretion. Table 1 summarizes these key points.

All changes were voluntary. No physician was forced to attend the conference or accept any modification proposed. The Institutional Ethics Committee approved the study.

In order to assess if the two angiography suites had similar radiation emission, we studied the fluence after 5 seconds of pulsed fluoroscopy at 7.5 ips and 15 ips and low and normal detail in a sample of 10 volunteers (6 male, 4 female; age, 32.9 ± 10.2 years; weight, 66.8 ± 10.2 K; height, 1.66 ± 0.1 m; body mass index, 24.0 ± 2.4 K/m²) evaluated in both rooms at x-ray tube height of 90 cm and x-ray field of 20 cm. There were 40 paired observations. There was no difference in fluence rates in both suites, with 17.1 ± 9.45 mGy-min⁻¹ and 16.7 ± 7.68 mGy-min⁻¹ (P=.56; r = 0.897 [95% confidence interval [CI], 0.81-0.94; P<.0001).

**Statistical analysis.** Continuous variables are expressed as means ± standard error of the mean (SEM) and categorical data as frequencies. After evaluation for data normality distribution by the Kolmogorov-Smirnov test, continuous variables with normal distribution were tested for differences using Student’s t-test, and Mann-Whitney was used for those without. Categorical data were compared using chi-square. All differences were considered significant if P≤.05.

Assuming a 40% reduction in Kₐ,r from 5 Gy to 3 Gy, a standard deviation of 3 Gy, with an alpha value of .01 and 100 patients in each group, the study would have a power of .98 to detect significant differences. Calculations were done with GB Stat and MedCalc statistical software.

**Results**

From September 2009 to August 2010, a total of 218 coronary angiographies plus angioplasties with stents ad hoc were performed. One or two lesions were treated in 53.9% and 26.7% of the cases, respectively. The mean number of implanted stents per patient was 1.91 ± .09. The femoral route was used in 82.5% and intravascular ultrasound in 33.5%. A single vessel was stented in 68% of cases and two major epicardial vessels were stented in 24.8%. In 16% true bifurcations and in 5.8% chronic total occlusions were treated.

There was a 38% reduction in Kₐ,r from 5.44 ± 0.30 Gy to 3.39 ± 0.22 Gy (P <.0001). PKA significantly decreased from 365.4 ± 21.1 Gy·cm⁻² to 233.7 ± 13.1 Gy·cm⁻² (P <.0001), representing a 36% reduction (Figure 1).

Not all physicians accepted a lower pulsed fluoroscopy ips rate, arguing insufficient imaging quality for a moving structure, but reduced both fluoroscopy and acquisition to 15 ips. All other interventionalists decreased fluoroscopy and acquisition rates to 7.5 ips and 15 ips, respectively. In those cases where the rate reduction was to 15 ips and 15 ips, there was a significant 33% and 34% decrease in Kₐ,r and PKA, whereas in those where the rate reduction was to 7.5 ips fluoroscopy and 15 ips acquisition, the decrease was 48% and 38% in Kₐ,r and PKA, respectively (Figure 2).

The physicians who attended the radiation conference at the end of the first 6-month study period had a significant reduction of 49% and 39% in Kₐ,r and PKA. Those who did not attend also had a significant reduction in Kₐ,r and PKA, of 23% and 33%. There was, however, a statistically significant 34% difference in Kₐ,r reduction during the second period among those who attended in comparison with those who did not (Figure 3).

According to the “radiation traffic light,” there was no difference in the distribution of low (Kₐ,r <2 Gy), yellow (Kₐ,r 2-5 Gy), and red (Kₐ,r >5 Gy) proportions in the first 6-month study period among all cardiologists prior to the instructional conference. There were significant differences in the distribution between groups that attended or not in the second half of the study (χ²= 12.2; P=.0022) (Figure 4).
Table 1. Key points to reduce radiation exposure to patients during coronary angioplasty.

- Modify pulsed fluoroscopy and acquisition rates to 7.5 ips and 15 ips, respectively
- Use low-detail fluoroscopy
- Take advantage of the “fluoro store” mode
- Minimize the use of acquisition mode (previously called cine)
- Avoid unnecessary recordings in acquisition mode (intravascular ultrasound runs, balloon inflations)
- Refrain from the use of magnifications
- Avoid steep angulations
- Avoid prolonged acquisition runs
- Maintain the image receptor as close to the patient as possible
- Use collimation to decrease scatter radiation
- Keep track of radiation emitted looking to data in the monitor or with help of devices such as a “radiation traffic light”
- Use the projections known to be associated with less radiation emission

Discussion

This study shows that physician awareness and compelling interest to decrease emitted radiation during angioplasties with very simple measures profoundly reduces the amount of radiation received by the patient, even beyond that achieved by decreasing pulsed fluoroscopy and acquisition rate by half.

Radiological protection protocols are important and possibly mandatory in every clinical field. Raff et al compared in a prospective controlled trial the dose of radiation emitted to patients undergoing cardiac CT angiography before and after optimizing the scan protocol, showing a 53.3% reduction in the estimated median radiation dose, without compromising image quality. Those findings are consistent with ours, since small technical adjustments may impact profoundly on the radiation received by the patient, even though it was a non-invasive study. There is an urgent need for widespread dose-reduction policies in all countries.

In general, cardiologists have sparse knowledge concerning the environmental impact of radiation and its biological risks, in spite of the fact that they order CT scans or nuclear tests. In a study by Correia et al, none of 100 cardiologists correctly answered all questions; in a simple four-item questionnaire, the global score by Correia et al, none of 100 cardiologists correctly answered all questions; in a simple four-item questionnaire, the global score was 0.85 ± 0.83. Training courses in radiological protection for physician or radiobiology and dose-decreasing techniques. Interestingly, our training course was a simple 2-hour conference, which was very effective. As Georges et al showed, with a 2-day protection course, the effect on dose reduction could persist for a long period, but it achieves its maximal effect by 3 months and then begins to dissipate. This suggests that it could be important to review this information at least every 6 months. As previously suggested, those interventionalists that expose patients to the highest radiation doses are less sensitive to dose reductions and possibly practice negligence.

Simple measures profoundly decrease radiation dose (Table 1). The coronary “default” frame rate should be modified from 15 ips and 30 ips in pulsed fluoroscopy and acquisition to 7.5 ips and 15 ips, respectively. The use of 15 ips pulsed fluoroscopy was associated with less K_{\alpha} reduction than 7.5 ips in this study, but it also was statistically significant. Avoiding unnecessary acquisitions is crucial, since the radiation dose duplicates compared to fluoroscopy; in those cases, such as balloon inflations or intravascular ultrasound positioning, the use of “fluoro store” may be sufficient. Increasing magnification will increase P_{\text{PKA}}, since a similar amount of radiation is applied to a smaller area. Decreasing the image field from 17 cm to 13 cm will increase 1.1 Gy in KA for every 100 Gy-cm\(^{-2}\) in P_{\text{PKA}}. Decreasing the length of each run will also reduce the radiation dose. As previously suggested, avoiding steep angles of x-ray beam decreases radiation doses.

Physicians performing angioplasty should have on-line information regarding the amount of radiation that has been used. Modern x-ray devices have incorporated dosimeters that can measure K_{\alpha} and P_{\text{PKA}}. However, the results, usually shown in the monitor next to the fluoroscopy image, are seldom appreciated. In order to improve information to physicians, we installed a “radiation traffic light” in the angiography suite. Levels for advising and the move from green to yellow and then to red were chosen based on known deterministic effects. NCRP report 168 suggests first notification at K_{\alpha} of 3 Gy and subsequent notifications every 1 Gy and P_{\text{PKA}} of 300 Gy-cm\(^{-2}\) and 100 Gy-cm\(^{-2}\), respectively.

There is an urgent need to establish diagnostic reference levels (DRL) for fluoroscopy-guided cardiac interventional procedures. Data heterogeneity, differences in practice patterns, complexity of procedures, and patient characteristics make this complicated. Approaches among countries differ; in some cases, K_{\alpha} and P_{\text{PKA}} are used at a level that may cause radiobiological damage, while in others, DRLs are based on 75th percentile. The latter is based on the belief that DRL should be set at a value that is not expected to be exceeded in a standard procedure when normal practice is applied, and it should not be set so high that it is never surpassed, keeping in mind the balance of a good-quality image at the lowest radiation exposure, ie, the ALARA (As Low As Reasonably Achievable) principle. For this reason, the third-quartile values are regularly used in establishing DRL, with the assumption that 25% of procedures could benefit from reducing dose levels. Our practice is to perform most angioplasties at the same time as angiography, thereby increasing the radiation dose. The International Atomic Energy Agency reported a multinational study with 817 coronary angioplasties at the time of angiography, showing a 75th percentile for K_{\alpha} at 2.7 Gy and for P_{\text{PKA}} at 138.3 Gy-cm\(^{-2}\), and suggested reference levels of P_{\text{PKA}} for coronary angiography and angioplasty of 50 Gy-cm\(^{-2}\) and 125 Gy-cm\(^{-2}\), respectively. In the DIMOND program, proposed reference levels based on 75th percentile were a P_{\text{PKA}} of 94 Gy-cm\(^{-2}\) for...
angioplasty and 57 Gy·cm\(^2\) for coronary angiography.\(^{20}\) According to these principles, after adjusting the x-ray console and instructing physicians, our 75th percentile \(K_a\) and \(P_{\text{MB},a}\) were 4.63 Gy and 322 Gy·cm\(^2\), far above those previously reported. With these radiation levels, it is difficult to sustain the 75th percentile principle for good practice in a particular hospital environment instead of setting a fixed upper level for permitted radiation. In any case, decreasing radiation emitted to the patient should be a continuous quest, and radiation metric comparisons must be repeated frequently.

Assuring a good quality practice in every catheterization laboratory is a responsibility of any society. Quantifying and reporting radiation dose levels in the patient chart are now mandatory in our hospital. A good planning of the intervention with all information, preferably avoiding repetitive studies where radiation is involved, is desirable. Continuous surveillance for possible late deterministic events in every laboratory in order to obtain appropriate information regarding its incidence and consequences is also advisable.\(^{7,23,24}\)

**Study limitations.** This is a single-center study with a low volume and relatively simple cases. The educational intervention provided to the physicians participating in the study was not randomized and therefore possibly biased, since the group of physicians who chose not to attend the educational program may be predisposed to being less concerned about radiation safety and thus less likely to aggressively lower doses. As previously shown,\(^{10}\) training in radiation protection for interventional cardiologists was associated with a 50% reduction in radiation exposure to patients undergoing invasive cardiac procedures; therefore, we do not believe that a randomized trial in order to answer this question would be ethical, thus this is the best level of information available. Furthermore, the local regulation agency recently published the requirements for training in radiological safety and protection for sanitary personnel involved with ionizing radiation, making randomization possibly even unallowable.\(^{25}\)

Also, we did not randomize the use of the “radiation traffic light,” therefore we were not able to assess its impact on the radiation emissions. It would be of great interest for a future study to randomize the use of this simple feedback method of radiation emission. Newer interventional suites such as the Artis Zee from Siemens AG have incorporated this accessory into the procedural information display.

Although we did not randomize the use of the angiography suite, we studied the fluence in each room and found that there was no difference in radiation emission in a sample of 40 comparative volunteers; therefore, it is unlikely that there was a difference in x-ray efficiency between the rooms and thus was unrelated to the new knowledge base provided by the 2-hour course.

Though suggested by the finding that the amount of radiation received by the patient was less in those performed by physicians attending the instructional conference, we have no way to prove that it had a direct impact upon the amount of radiation emitted, since we have no registry upon the angiulations, use of collimators, magnifications, and source-to-image receptor distance.

The main endpoint of the trial, radiation dose, was not measured directly, with skin dosimetry. Bogaert et al showed a good correlation of skin dosimetry and the readings from the collimator, when \(P_{\text{MB},a}\) is multiplied by a conversion factor of 1.03 (a 3% difference).\(^{23}\)

**Conclusion**

A judicious balance between good imaging and low radiation during coronary angioplasty requires special effort, focusing on using low fluoroscopy and acquisition rates, large image fields, collimation, short runs, appropriate projections, and instant feedback. This requires not only modifications in computational parameters of the x-ray equipment, but also knowledge and commitment of the interventionalist, who can improve both with adequate instruction.

**References**