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Radiation reduction during percutaneous coronary intervention

A new protocol with a low frame rate and selective fluoroscopic image storage

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Abstract

The percutaneous coronary intervention (PCI) procedure is associated with potentially high levels of radiation exposure and therefore increased risk of adverse radiation-induced outcomes, ranging from cataract to malignancy. Frame rate reduction and selective fluoroscopy storage may help reduce radiation exposure. In this study, we evaluated the efficacy of a radiation reduction protocol that uses a lower frame rate and selective storage of fluoroscopic images in terms of its effect on reducing the radiation dose during PCI.

The new protocol incorporated a lower frame rate as compared with the conventional protocol, and used selective storage of fluoroscopic images. We reviewed the medical records of patients who underwent PCI under the conventional protocol from January 2013 to December 2013, and compared them with those who underwent PCI with the new protocol from January 2015 to December 2015. The primary endpoint was radiation dose reduction expressed as cumulative air kerma and dose-area product (DAP). The image quality was assessed by 3 independent well-trained cardiologists.

One hundred fifty-five patients were enrolled in the conventional protocol group, and 152 were enrolled in the radiation reduction protocol group (total, n=307). There was no statistical significance in terms of the baseline characteristics, including body mass index. Overall, the radiation reduction protocol group showed a significant reduction in both cumulative air kerma (1634.39 ± 717.95 vs 2074.75 ± 1003.72 mGy, $P<.001$) and DAP (12344.86 ± 5371.75 vs 15312.19 ± 7136.58 μGy m^2, $P<.001$). Image quality was acceptable in both groups.

The radiation reduction protocol, which uses a lower frame rate and selective storage of fluoroscopic images, may be an alternative approach to reducing PCI radiation dose.

Abbreviations: AK = air kerma, BMI = body mass index, CAG = coronary angiography, CTO = chronic total occlusion, DAP = dose-area product, PCI = percutaneous coronary intervention.

Keywords: fluorography, frame rate, percutaneous coronary intervention, radiation hazards

1. Introduction

Percutaneous coronary intervention (PCI) has played an essential role in the treatment of coronary artery obstructive disease, and most PCIs are performed with fluoroscopic guidance using ionizing radiation. Over time, as the procedure has become progressively more complex due to anatomical challenges, the presence of calcified lesions, and chronic total occlusion (CTO), the radiation dose applied to both the patient and the operator has increased. As an elevated radiation dose is linked to specific health hazards ranging from cataracts to malignancy,[1] cardiologists are interested in minimizing radiation exposure. Technological developments have provided various novel strategies for reducing radiation dose, including upgraded software for modern angiographic systems that enable control of both the frame rate of fluoroscopy and fluoroscopic image storage. Studies have shown that a decreased frame rate during fluoroscopic guidance and cineangiography effectively reduces radiation,[2] and that selective fluoroscopic storage, instead of cineangiography, is even more effective for reducing radiation.[3,4]

There are limited data available on the use of this method, which has been applied to real clinical practice for a long period. In this study, we hypothesized that a radiation reduction protocol using a low frame rate and selective fluoroscopic image storage would most successfully reduce the radiation dose, and applied this protocol to real-world practice. In this article, we determine the effectiveness of the new protocol in reducing the radiation dose during PCI in comparison with the conventional protocol in the real world.

2. Participants and methods

In 2014, we explored various approaches to shifting the conventional PCI protocol to the radiation reduction protocol, and the established radiation reduction protocol was launched at

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the beginning of January 2015. Before the implementation of the radiation reduction protocol, fluoroscopic and cineangiographic images were acquired at a rate of 15 frames/s and recording for all procedures was performed by cineangiography. However, once the new protocol was introduced, the fluoroscopic guidance was reduced to 7.5 frames/s and the cineangiographic acquisition to 10 frames/s, respectively. In addition, the use of cineangiography was limited to the baseline coronary angiography (CAG), subsequent CAG, stent positioning, and final CAG, whereas other procedures such as balloon inflation, stent insertion, thrombus aspiration, and intravascular ultrasonography were recorded with selective fluoroscopic image storing. Conversion to a higher frame rate and expanded use of cineangiography were allowed if the image quality was poor during the procedure, at the operator's discretion.

We reviewed the data of consecutive patients who underwent coronary intervention at our cardiac catheterization laboratory from January 2013 to December 2013 for the conventional protocol group, and from January 2015 to December 2015 for the radiation reduction protocol group. Patient demographic information relevant to radiation dose analysis, such as body mass index, was collected from the laboratory database.

All procedures were performed by only 1 operator to remove interoperator variation. All procedures were conducted with an Artis zee CAG system equipped with the software version VC21B and a ceiling-mounted lead shield (Siemens AG; Erlangen, Germany). A built-in "Store fluoro" function was used for selective fluoroscopic image-saving.

Both patients who underwent emergency procedures and those who underwent procedures for chronic total occlusion (CTO) were excluded because the typical emergency procedure is rarely performed within the routine protocol, and the CTO procedure requires a high frame rate to facilitate the location of communicating channels. Patients who underwent procedures for which there was no information available regarding the radiation dose applied were also excluded. The design of this retrospective study was approved by our institutional review board. We were exempted from obtaining informed consent by the committee, as this was a retrospective study.

The primary endpoint of this study was radiation dose reduction as measured at an interventional reference point (Ka, r) in the form of air kerma (AK; mGy), and the dose-area product (DAP; $\mu Gy\,m^2$). AK is defined as the radiation dose per unit mass of air (kg), whereas the definition of DAP is the product of AK in the exposed area. Total fluoroscopic time was also documented.

Three experienced interventional cardiologists, who each had an experience of >5 years in interventional cardiology, reviewed the angiographic images for objective analysis of angiographic image quality. They were blinded to the patient data and to the PCI protocol. Image quality was judged on a 10-point scale, with the ideal image for decision-making having a score of 10 and the image not suitable for analysis having a score of 1. The score represented the entire study, not an individual image. To adjust for interobserver variations, each participating cardiologist reviewed an additional 5 common cases, and all reviewers' scores were recalibrated from the median scores for the commonly reviewed cases.

Continuous variables were expressed as means ± SD, and categorical variables were expressed as percentages. In the analysis for statistical significance, a t test was used for continuous variables, whereas the χ^2 test was used to test for categorical variables. The software SPSS version 18.0 (SPSS Inc., Chicago, IL) was used for all statistical analysis.

3. Results

We reviewed the medical records of 194 patients who underwent coronary PCI between January 2013 and December 2013, and 189 patients who underwent coronary PCI from January 2015 to December 2015. Four patients in the conventional group were excluded from the study because they had undergone the emergency procedure. In addition, 72 participants (35 in the conventional protocol group and 37 in the radiation reduction protocol group) were excluded because they had undergone a CTO procedure. There were also 4 participants in the conventional protocol group whose radiation data were missing; these patients were excluded from this study as well. Ultimately, 307 patients were analyzed, including 155 in the conventional protocol group and 152 in the radiation reduction protocol group (Fig. 1). Conversion to a high frame rate and an increased use of cineangiography during the procedure occurred only in 9 cases in the radiation reduction protocol group.

Baseline characteristics including body mass index (BMI), sex, and age presented no statistically significant differences between the 2 groups. In terms of procedural characteristics, the number of target vessels and inserted stents was relatively similar between the 2 groups. The use of the femoral approach was relatively higher in the radiation reduction protocol group, although there was no significant statistical difference between the levels of use in the 2 groups (Table 1).

The radiation dose, as measured by total AK and DAP, was significantly lower in the radiation reduction protocol group than in the conventional protocol group (1634.39 ± 717.95 vs 2074.75 ± 1003.72 mGy, $P < .001$ and 12344.86 ± 5371.75 vs 15312.19 ± 7136.58 $\mu Gy\,m^2$, $P < .001$, respectively) (Fig. 2). Total fluoroscopic time was not statistically different between the 2 groups (the radiation reduction protocol vs the conventional protocol, 16.15 ± 8.81 vs 15.89 ± 9.94 min, $P = 0.81$) (Table 2).

The image quality of most cases was adequate for decision-making, and there was no statistical significance in the image quality analysis. Although the image quality score was slightly higher in the conventional protocol group, the results of the analysis of angiographic image quality found no significant differences between the 2 groups in terms of unadjusted angiographic image quality scores (the conventional protocol group, 8.61 ± 0.91 vs the radiation reduction protocol group, 8.43 ± 0.86; $P = 0.089$) and those adjusted for potential interob-

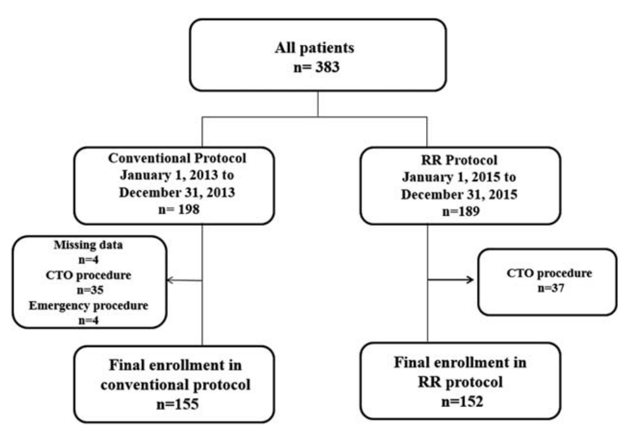

Figure 1. Patients included in this study. CTO = chronic total occlusion, RR = radiation reduction.

Table 1

Patient demographics and procedural demographics.

	Conventional protocol (n=155)	Radiation reduction protocol (n=152)	*P*
Age (y)	64.7±11.26	64.67±11.0	.984
Male	112 (72.3%)	110 (72.4%)	.983
Body weight (kg)	64.78±11.41	66.37±10.98	.213
Height (cm)	163.67±9.18	164.24±8.83	.580
Body mass index	24.06±2.85	24.56±3.31	.155
DM	55 (35.5%)	65 (42.8%)	.191
Hypertension	91 (58.7%)	92 (60.5%)	.746
Creatinine (mg/dL)	0.97±0.30	0.99±0.70	.680
Radial approach	119 (76.8%)	102 (67.1%)	.059
Number of stents/PCI	1.52±0.73	1.58±0.89	.501
Target vessels/PCI (number)	1.21±0.44	1.28±0.55	.176

All values are described as mean±SD or as a number (%).
DM = diabetes mellitus, PCI = percutaneous coronary intervention.

Table 2

The radiation dose results.

	Conventional protocol (n=155)	Radiation reduction protocol (n=152)	*P*
Total air kerma (mGy)	2074.75±1003.72	1634.39±717.95	<.001
Total dose-area product (μGy m²)	15312.19±7136.58	12344.86±5371.75	<.001
Total fluoroscopic time (min)	15.89±9.94	16.15±8.81	.810

All values are described as mean±SD or as a number (%).

server variability in image quality assessment (the conventional protocol group, 8.43±0.77 vs the radiation reduction protocol group, 8.27±0.77; $P=0.066$). These results showed that the image quality of the radiation reduction group was within acceptable limits, although it was lower than that in the conventional protocol group.

4. Discussion

From these meaningful results, we were able to demonstrate that the radiation reduction protocol we used, with a low frame rate and selective fluorography storage, was effective at reducing radiation. Interestingly, the total AK and DAP was significantly lower in the radiation reduction protocol group, and the overall magnitude of reduction in air kerma was about 21%. Total fluoroscopic time did not significantly differ between the 2 groups.

There are 2 categories of radiation hazards: deterministic and stochastic.[1] The deterministic type occurs due to an increase in radiation severity above a certain threshold, such as skin damage.[5,6] Stochastic hazards have a probabilistic effect without a particular threshold, such as malignancy and teratogenicity.[7] Recent reports have suggested the potential for an excess risk of brain tumors among interventional cardiologists.[8] Therefore physicians have a responsibility to ensure radiation safety for both the patients being evaluated and themselves, based on an "as low as possible" principle.[9]

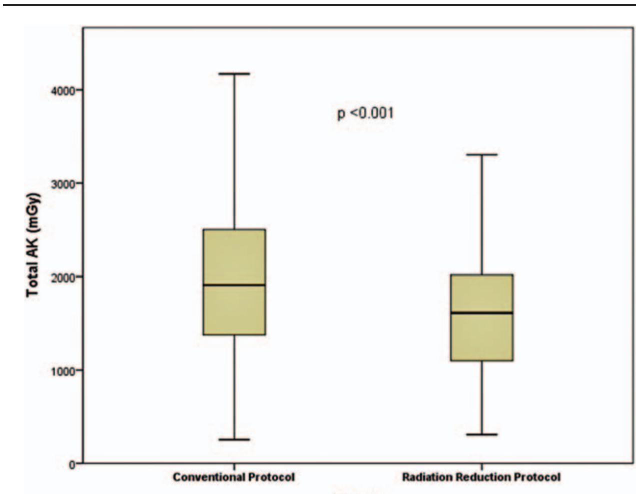

Figure 2. Effect of the radiation reduction protocol on total air kerma. Total air kerma was significantly lower in the radiation reduction protocol group.

Generally, radiation dose varies depending on BMI, age, sex, and procedure complexity.[10–12] In this study, there was no significant difference in these parameters between the 2 groups. There are other factors that influence radiation dose, such as time on beam, collimation, magnification, copper filtering and pulsing, and detector entrance dose.[13] In the 2004 ACCF/AHA/HRS/Society for Cardiac Angiography and Interventions Fluoroscopy Clinical Competence Statement, the following strategies were recommended for the safe use of medical radiation: minimizing beam on time and magnification, use of beam collimation, optimizing distance from source to the patient, and varying the entry site of radiation.[14] Developments in modern fluoroscopic technology have presented further options for reducing radiation. Wassef et al demonstrated that fluoroscopic and cineangiographic images with a low frame rate could reduce radiation dose without extensively diminishing image quality.[2] Other studies showed that fluorography with retrospective fluoroscopic image storage, instead of cineangiography, effectively decreased radiation dose.[4] Normally, cineangiography is used for recording procedures from multiple angles, such as during ballooning at the lesion, but the importance of such images is relatively minor during PCI. In this study, we adjusted the protocol to include a lower frame rate and the use of fluorography to record procedures in lieu of cineangiography. This protocol is simple and practical in an actual interventional setting, and the results showed a decreased radiation dose in the radiation reduction protocol group without any increase in fluoroscopic time.

To the best of our knowledge, this is the first report to use a simple revised PCI protocol with a lowered frame rate and selective fluoroscopic image store with the aim of reducing radiation dose. Moreover, this study presents data from an actual clinical scenario in which the 2 protocols were each utilized for 1 year, respectively. Nevertheless, our study has some limitations. First, it was conducted using modern fluoroscopic technology that regulates frame rate and offers selective fluoroscopic image storage. Therefore, we cannot generalize our results to all clinics because older fluoroscopic machines without the frame rate regulation capability are still used in many cardiac catheterization laboratories. Second, this study did not measure the radiation dose directly affecting the human body; instead, the influence on the human body was assumed to be indirectly reduced by confirming the reduction of the overall radiation dose. Lastly, this study was not a randomized study, and was a singlecenter assessment with a small number of patients; therefore, a prospective randomized multicenter trial is needed to validate the results.

In conclusion, the radiation reduction protocol substantially reduced the procedural radiation dose as compared with the conventional protocol. Thus, the radiation reduction protocol, with its low frame rate and selective fluoroscopic image storage, may be recommended as a useful approach for reducing radiation exposure during PCI.

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