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Utilization of Dose Management Protocol in the Cardiac Catheterization Laboratory: Evaluating the Effects of Reducing Frame Rate and Cine Dose Together for Angiography

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Abstract

Background: Although radiation is beneficial for invasive procedures, it can be harmful. Several factors such as equipment settings, patient characteristics, and a physician's procedure affect the dose of such radiations. Here we aimed to evaluate the X-ray dose and image quality after reducing both the default rate (frames per second: f/s) and cine exposure dose for coronary angiography.

Methods: The study retrospectively reviewed 215 patients who underwent with a standard frame rate and standard cine dose (15 f/s and 0.200 µGy/fr) or a low frame rate and low cine dose (7.5 f/s and 0.120 µGy/fr, referred to as dose management protocol: DMP group). All the patients were performed diagnostic angiogram without additional therapy. The primary endpoint was total air kerma (AK; mGy), and the secondary endpoints were radiation time, contrast volume, procedure complication rate, and a 10-point scale to assess the image quality.

Results: There were no differences with regard to baseline demographics and risk factors between both the groups. Total X-ray dose was significantly low in the DMP group compared with the standard group (181.4 mGy vs. 352.7 mGy; $p<0.01$). There were no differences with respect to radiation time, contrast volume, and complication rate between both the groups. The diagnostic value in the DMP group was not inferior to that in the standard group (8.79 ± 1.05 vs. 8.91 ± 0.91; $p=0.37$).

Conclusions: Our innovative alteration of reducing both the frame rate and cine dose for angiography can dramatically decrease the total AK without sacrificing image quality.

Keywords: Coronary angiography; Radiation management; Fluoroscopy; Imaging quality

Abbreviations: f/s: Frames Per Second; DMP: Dose Management Protocol; AK: Air Kerma; BMI: Body Mass Index; PCI: Percutaneous Coronary Intervention; CAG: Coronary Artery Angiography

Introduction

X-ray fluoroscopy and cine fluorography are core imaging techniques that facilitate invasive cardiovascular procedures. Although these procedures result in many patients receiving numerous diagnostic and therapeutic benefits, the use of ionizing radiation represents an associated hazard that should be justified by the benefits of the procedure [1]. As these procedures have become increasingly complex, they may involve fluoroscopy being performed for longer durations that may lead to patients being exposed to higher radiation levels [2].

The use of ionizing radiation is governed by the core principle as low as reasonably achievable (ALARA). The ALARA principle recognizes that there is no magnitude of radiation exposure that is known to be completely safe [3,4]. Because X-ray scattering from the dose administered to a patient constitutes the primary source of radiation exposure among physicians and staff, efforts to reduce the dose administered to patients will also reduce the total operator dose [5,6]. The amount of X-ray exposure during invasive coronary angiography is strongly associated with the exposure dose (µGy/fr) and the number of frames per second (f/s). Currently, in most catheterization laboratories, the cine exposure dose used is 0.200 µGy/fr and the frame rate is 15 f/s, which are acceptable for cardiologists.

This study aimed to assess radiation exposure and image quality after reducing the cine exposure dose from 0.200 µGy/fr to 0.120 µGy/fr and the frame rate from 15 f/s to 7.5 f/s for fluoroscopy and cine angiography (Figure 1) to determine whether the reduced levels of these variables can be generally applied in catheterization laboratories.

Methods

Study population

From March 2014 to August 2015, we retrospectively reviewed 215 patients who underwent coronary artery angiography (CAG) performed by three experienced academic cardiologists at Beijing Anzhen Hospital. The patients underwent their procedure with a standard frame rate and standard cine dose (standard group) or with a low frame rate and low cine dose. Only those patients who underwent elective procedures were included in the study. Patients who presented

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with acute myocardial infarction for emergency procedures were excluded. All patients provided written informed consent for the procedure, and the institutional review board approved this study. All studies were performed with a right radial approach.

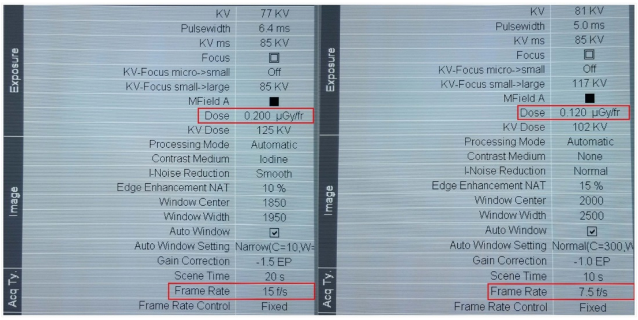

Figure 1: Control panel for the Siemens Artis Zee Floor. (A) The settings for the standard group: 15 frame per second and cine exposure dose of 0.200 µGy/fr; (B) The settings for the DMP group: 7.5 frames per second and cine exposure dose of 0.120 µGy/fr.

X-Ray dose assessment

In Beijing Anzhen Hospital, there are 16 catheterization laboratories. For this study, we selected three laboratories that used an angiographic system (Artis Zee Floor; Siemens Healthcare GmbH, Forchheim, Germany). In the standard group, the patients underwent angiography using the standard dose protocol; for the procedure, both fluoroscopy and cine angiography were performed with a frame rate of 15 f/s and a cine exposure dose of 0.200 µGy/fr. In the DMP group, the patients underwent angiography using DMP; here fluoroscopy and cine angiography were performed with a frame rate of 7.5 f/s and a cine exposure dose of 0.120 µGy/fr. The total X-ray dose (also referred to as the air kerma: AK) generated by the angiographic system for each case was recorded in a database. The fluoroscopy time was defined as the time during which fluoroscopy was performed during the procedure. Total AK at the interventional reference point (mGy) was defined as cumulative AK at the interventional reference point. Radiation exposure of physicians was not directly measured in this study. We focused on other variables such as maximizing the table height, configuring the magnification to 22 cm, making the angulation of the camera as consistent as possible, and standardizing the number of images and image acquisition time. To ensure the diagnostic adequacy of the study, any or all variables could be changed at the operator's discretion. All data on deviations from the previously mentioned variables were collected for comparison between the two groups.

Cardiologists and CAG

Three professors with the Chinese physician's license for performing percutaneous coronary intervention (PCI) participated in this study. They were all engaged in PCI operations for more than 10 years. Three fellows of the Chinese Association of Cardiovascular Intervention were also included in our team. During the procedure, each professor and each fellow performed angiography together; thus, a total of six cardiologists participated in this study. Although there were no standard protocols for angiography, we list several basic principles in this study. (a) Patients for whom the right radial approach was not used were excluded. (b) The minimal number of cine was six. (c) Before the study, the importance of using optimal radiation practices was emphasized to all participants, including the use of less extreme angulations, maximal collimation, reduction in source-to-detector distance, and decreased geometric magnification by decreasing the source-to-object distance. Adherence to all of these principles would reduce the influence of individual differences among both cardiologists and patients on the study results.

Endpoints

The primary endpoint was total AK at the interventional reference point (mGy), which was defined as the cumulative AK at the interventional reference point [5]. The secondary endpoints were fluoroscopy time, defined as the time in which fluoroscopy was used during a procedure; contrast volume; and procedure complication rate (excluding radial approach complications not needing X-ray). The secondary endpoints also included assessment of angiographic image quality. To objectively evaluate image quality, we designed a 10-point scale, in which 10 was the best quality, including several assessed aspects such as image definition, image fluency, and noise tolerance. We then designed an index of diagnostic value, which would enable comprehensive evaluation of the procedure, was defined the ability of achieving diagnostic angiography, the high scores meant we could use this protocol to diagnose coronary artery disease. We selected all the angiograms from each group. The images were rated using the scale by other 10 experienced physicians to evaluate image quality.

Summary statistics (mean, SD, median, minimum and maximum values, and frequency distribution) were generated for the patients' demographic and baseline clinical data and outcome of interest by randomization arm. Graphical displays (box plots and histograms) were used to facilitate visualization of the distribution of each variable. Descriptive analysis was conducted whereby frequencies and percentages were used to describe demographic characteristics. The Chi Square test was used to determine the categorical variables while Student's t-test was used to compare continuous data such as the primary endpoint of radiation exposure between the two groups using Student's t-test.

Results

In total, 215 patients were examined with regard to the outcome of the total X-ray dose administered. There were 106 and 109 individuals in the standard group (default pulse rate was 15 f/s for fluoroscopy and cine angiography and cine exposure dose was 0.200 µGy/fr) and the DMP group (default pulse rate was 7.5 f/s for fluoroscopy and cine angiography and cine exposure dose was 0.120 µGy/fr), respectively. Table 1 show that there were no differences in both the groups with respect to baseline demographics such as height, weight, and body mass index (BMI). The average age of patients in the standard and DMP groups was 62.4 years and 60.2 years ($p>0.05$), respectively, with 75.5% and 66.1% male predominance ($p=0.87$), respectively. For all patients, the radial artery was used for the procedure. Table 1 also reveals no significant differences between the two groups with respect to risk factors such as smoking, hypertension, diabetes, and hyperlipidemia ($p>0.05$).

The radiation exposure and X-ray dose are presented in Table 2. Total X-ray dose was significantly lower in the DMP group than in the standard group (181.4 mGy vs. 352.7 mGy; $p<0.01$). There were no significant differences between the two groups with regard to radiation

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time (110.4 s vs. 117.7 s), number of images per case (6.2 vs. 6.2), or volume of contrast (47.8 ml vs. 50.2 ml). In the standard group, one patient had brachial artery hematoma because of incautious wire manipulation. In the DMP group, no procedural complication rates were recorded, with no significant difference in this regard being identified between the two groups.

Variables	Standard Group	DMP Group	p-values
Demographics	106	109	
Age (years)	62.4 ± 12.4	60.2 ± 11.7	NS
Sex (% men, n)	75.5% (80)	66.1% (72)	0.87
Height (cm)	166.8 ± 10.2	169.6 ± 11.5	NS
Weight (kg)	72.5 ± 13.2	75.4 ± 14.5	NS
BMI (kg/m^2)	30.7 ± 4.5	29.5 ± 4.3	NS
Risk factors, % (n)			
Recent tobacco use	33% (35)	40.4% (44)	0.74
Diabetes	21.7% (23)	23.9% (26)	0.29
Hypertension	43.4% (46)	47.7% (52)	0.47
Hyperlipidemia	61.3% (65)	73.4% (80)	0.94

Table 1: Patient baseline characteristics for the standard and DMP groups.

Data of the 10-point scale that was used to assess image quality are presented in Figure 2. The low frame rate and low exposure dose in the DMP group significantly induced lower scores of definition and fluency than those in the standard group (8.83 ± 1.34 vs. 8.34 ± 0.97 and 9.03 ± 0.55 vs. 8.27 ± 0.64, respectively; p<0.01). The noise tolerance was acceptable in the two groups (8.43 ± 0.79 vs. 8.24 ± 0.93; p=0.11). Regarding the diagnostic value, which represented a comprehensive evaluation of the images, no significant difference was identified between the two groups (8.79 ± 1.05 vs. 8.91 ± 0.91; p=0.37). The W value (Kendall's coefficient of concordance W test) of agreement of all physicians in assessing the DSA imaging quality was 0.73 (p=0.038). Figure 3 shows several images of CAG for the same patient under two different criteria.

Variables	Standard Group	DMP Group	p-values
Total Air Kerma (mGy)	352.7 ± 87.5	181.4 ± 62.3	p<0.01
Radiation time (s)	110.4 ± 42.4	117.7 ± 38.3	NS
Number of images	6.2 ± 0.8	6.2 ± 0.7	NS
Contrast volume (ml)	47.8 ± 20.5	50.2 ± 23.4	NS
Procedural complication rates (%)	0.94%	0%	NS

Table 2: Radiation exposure and procedure demographics for the standard and DMP groups.

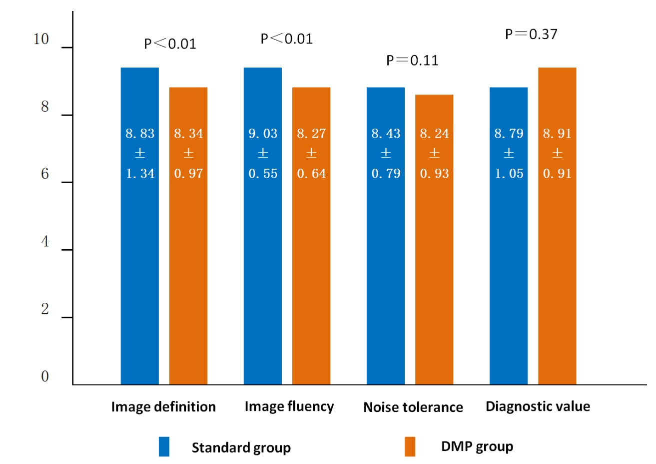

Figure 2: Angiographic quality assessment for the standard and DMP groups.

Regarding the diagnostic value, which represented a comprehensive evaluation of the images, no significant difference was identified between the two groups (8.79 ± 1.05 vs. 8.91 ± 0.91; p=0.37). The W value (Kendall's coefficient of concordance W test) of agreement of all physicians in assessing the DSA imaging quality was 0.73 (p=0.038). Figure 3 shows several images of CAG for the same patient under two different criteria.

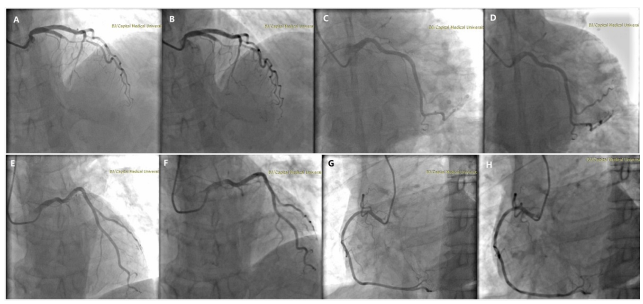

Figure 3: Coronary angiography under different settings for the same patient. (A,C,E,G) Standard settings: 15 frames per second and cine exposure dose of 0.200 μGy/fr. (B,D,F,H) DMP settings: 7.5 frames per second and cine exposure dose of 0.120 μGy/fr.

Discussion

In this retrospective study, a significant reduction in X-ray dose was observed when DMP was used during the angiography procedure; DMP included decreasing the exposure dose from 0.200 μGy/fr to 0.120 μGy/fr for cine angiography and decreasing the frame rate from 15 f/s to 7.5 f/s for both fluoroscopy and cine angiography. Baseline demographics, including weight and BMI, of patients, which can significantly influence the results of the X-ray dose, showed no significant differences between the two groups. Regarding the primary endpoint, total X-ray dose was significantly lower in the DMP group than in the standard group (181.4 mGy vs. 352.7 mGy; p<0.01). Regarding the secondary endpoints, fluoroscopy time, contrast volume, and procedure complication rate did not increase with total AK reduction. Moreover, although combined reduction of the dose and frame rate influenced image fluency, dose reduction alone inevitably influenced image definition and increased signal noise. However, all the experienced cardiologists considered the image quality to be acceptable, and they could successfully achieve diagnosis. Therefore, this simple method of changing the procedure of coronary angiography can reduce radiation exposure for both patients and cardiologists.

China has become the country with the second highest number of interventional cardiology procedures performed globally. In 2016, Chinese cardiologists performed >660,000 PCI. However, despite this, the awareness regarding the damage potentially caused by X-ray exposure has remained at a basic level among Chinese physicians. To our knowledge, this is the first study wherein both the frame rate and cine exposure dose were decreased for angiography, demonstrating that these two combined reductions can dramatically decrease total AK without sacrificing the image quality.

Although ionizing radiation is very beneficial for invasive procedures, it can be harmful [7-11]. When used in small amounts, the risk for a harmful reaction is very small. However, as the dose increases, the risk also increases. Furthermore, above a certain threshold, the risk can be substantial, causing severe patient injury [12,13]. Physicians who administer the radiation to patients should employ a risk-benefit analysis, similar to that used when prescribing prescription drugs. To make informed decisions, the physician must understand the association between exposure to radiation and the potential consequences for health [14,15]. ACCF/AHA/HRS/SCAI have published a radiation management protocol for invasive cardiovascular procedures [16] and have summarized factors that affect the dose in interventional procedures, including equipment design and settings, patient factors, and the physician's procedure. Although patient characteristics cannot be controlled, increasing the awareness and the ability of physicians in managing radiation exposure is an efficient method for reducing the X-ray dose. Shikhar et al. [17] used a series of measures, including the use of less extreme angulations, maximal collimation, reduction in source-to-detector distance, increased field of view, and decreased geometric magnification by decreasing source-to-object distance, to reduce the radiation dose in catheterization laboratories; these methods can be controlled by physicians, thereby demonstrating that the physician's exposure to radiation could be dramatically reduced. Farajollahi et al. [18] found that specific angiographic projections expose patients to significantly higher radiation; thus, these projections should be avoided and replaced by less irradiating projections whenever possible. This demonstrates that physicians play important roles in reducing exposure dose. In our catheterization laboratories, all staff potentially exposed to radiation should be trained twice a year to increase their awareness regarding the importance of protection. Our study emphasizes a third set of factors that are important in this context, namely equipment design and settings. In most SIMENS catheterization laboratories, the standard cine dose is 0.200 μGy/fr and the frame rate is 15 f/s, implying that the cine exposure dose per second is as follows:

$0.200\ \mu Gy/fr \times 15\ f/s = 3\ \mu Gy/s$.

In the DMP group, the settings included cine exposure dose of 0.120 μGy/fr and frame rate of 7.5 f/s; thus, the cine exposure dose per second was as follows:

$0.120\ \mu Gy/fr \times 7.5\ f/s = 0.9\ \mu Gy/s$.

$0.9\ \mu Gy/s \div 3\ \mu Gy/s = 0.3$.

In theory, changing the cine exposure dose and frame rate can decrease the X-ray dose by 70%. Because of individual differences, our study shows that in the DMP group, the X-ray dose decreased by 51.4% on an average. Therefore, both the theoretical and actual results demonstrate that our method can dramatically reduce the dose.

To assess image quality, we designed a 10-point scale that included three aspects of assessment and that established the diagnostic value as an index that reflected a comprehensive judgment of the images. Although the frame rate of 7.5 f/s influenced image frequency, at our department, physicians have accepted the use of 7.5 f/s to be a routine criterion for angiography, even in procedures involving stent implantation. In addition, reducing the cine exposure dose inevitably impairs the image definition. Therefore, under specific circumstances, such as detecting the proximal cap of a chronic total occlusion lesion, we recommend using the standard cine exposure dose for angiography. However, our study demonstrates that the diagnostic value in the DMP group was excellent and acceptable for angiography. Several studies have investigated innovative methods that can reduce the X-ray dose. For example, Pyne et al. [19] compared a standard dose cohort (15 f/s for fluoroscopy and cine angiography) and a reduced dose cohort (10 f/s for fluoroscopy and cine angiography), revealing that the reduced dose cohort exhibited a significant reduction in the mean total X-ray dose (1763.1 mGy vs. 1179.1 mGy; p<0.0001). In addition, Sadamatsu et al. [20] described that a change in the frame rate from 15 f/s to 7.5 f/s for fluoroscopy could significantly reduce AK (701.4 ± 427.9 mGy vs. 936.8 ± 623.9 mGy; p=0.02). Moreover, Hansen et al. [21] found that when the frame rate was decreased from 10 to 7.5 f/s during the PCI procedure, AK significantly reduced (703.0 vs. 621.0; p=0.041). There was no difference between the two groups with regard to complications and MACE at 30 days and 6 months. Ebrahimi et al. [22] performed a randomized trial, 39 consecutive patients referred for coronary angiography were assigned in a 1:2 ratio to have their procedure performed at 15f/s and 7.5f/s, respectively. Total radiation exposure was significantly less in the 7.5 f/s groups as opposed to 15 f/s group (252.2 mGy vs 433.7 mGy, p<0.01). Werner et al. [23] analyzed a consecutive cohort of 984 PCIs for chronic total occlusions in 863 patients between January 2010 and July 2015. They found there was a significant reduction of Air Kerma from period J-score 2 to 3 from 3.5 Gy to 2.7 Gy, which demonstrated dose management strategy also applied to stenting procedure.

Conclusion

As in other retrospective studies, our study also has some limitations. First, this type of design is inevitably associated with a selection bias. Second, although all three physicians had comprehensive experience of interventional cardiology, their individual operating styles probably influenced the results. Third, the single-institution design of this study is another limitation; hence, a further multicenter validation of these results is required. Finally, the system for assessing image quality is not completely objective.

To adhere to the ALARA principle, we explored an innovative method to reduce the X-ray exposure dose without sacrificing the image quality. Our study demonstrated that the total X-ray exposure dose was significantly lower when the cine exposure dose decreased from 0.200 μGy/fr to 0.120 μGy/fr and frame rate decreased from 15 f/s to 7.5 f/s for fluoroscopy and cine angiography, and the diagnostic value of this new method was satisfactory among the physicians. There is significant benefit in reducing the frame rate and cine exposure dose, which have been preliminarily verified in this study and should be generally applicable in more catheterization laboratories.

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Conflicts of Interest

None.

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