

Randomized Study of the Safety and Clinical Utility of Rotational Angiography Versus Standard Angiography in the Diagnosis of Coronary Artery Disease

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This study evaluates the safety and clinical utility of rotational angiography in the diagnosis of coronary artery disease. High-speed rotational angiography is a newly available angiographic modality that gives a dynamic multiple-angle perspective of the coronary tree during a single contrast injection. We prospectively randomized 56 patients referred for diagnostic coronary angiography to either standard or rotational angiography. Contrast and radiation utilization were compared between the two groups. The number of additional cine acquisitions needed was used to determine adequacy of the diagnostic study protocol. Rotational angiography was successfully completed in all subjects. There was a 33% reduction in contrast utilization in the rotational group as compared to the standard group (35.6 ± 12.6 vs. 52.8 ± 10.7 ml, respectively; $P < 0.0001$). Additionally, there was a 28% reduction in total radiation exposure in the rotational group as compared to the standard group (39.0 ± 18.5 vs. 53.9 ± 23.4 Gy cm^2 , respectively; $P = 0.01$). Total whole-body radiation exposure to the primary operator was 144 mrem with rotational angiography and 170 mrem with standard angiography. Procedure time tended to be shorter for rotational angiography (353.9 ± 146.7 vs. 396.8 ± 165.8 s; $P = 0.3$). Rotational coronary angiography can be rapidly performed in any patient and provides a significant reduction in contrast and radiation utilization while at the same time providing adequate angiographic data to complement or replace standard coronary angiography in the evaluation of coronary artery disease. *Catheter Cardiovasc Interv* 2004;62:167–174.

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INTRODUCTION

Coronary angiography is one of the most commonly performed invasive diagnostic procedures in the world. Despite being a great technological leap in the evaluation of patients with coronary artery disease (CAD), the current practice of standard fixed-view coronary angiography has several limitations. Studies of intravascular ultrasound, angioscopy, and pathologic analysis have demonstrated the limited diagnostic accuracy of coronary angiography [1–7]. Standard angiography gives a fixed perspective of the coronary tree, which limits the amount of information that can be obtained. Angiographic views are traditionally operator-selected in order to minimize vessel overlap and foreshortening subjectively. Typically, the angiographer will arbitrarily pick the initial views and then determine what other image acquisitions are needed to visualize adequately the entire coronary tree. The multiple fixed snapshots of the coronary tree are then pieced together by the operator to reconstruct mentally the complex three-dimensional coronary anatomy. Critical to planning coronary interventions, this informa-

tion is then used to determine vessel size, lesion severity, lesion length, lesion morphology, and side-branch involvement. However, the degree of lumen narrowing, lesion length, and plaque morphology have not been reliably predicted by standard angiography, particularly

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in the presence of complex or eccentric lesions [5–9]. Errors in angiographic interpretation have clinical significance and may affect patient management [10,11]. Suboptimal projections and incomplete exploitation of the angiographic information obtained from standard angiographic images may explain at least some of the diagnostic inaccuracy that have been reported in the past few decades. Standard angiography not only has imperfections based on the known limitations of fixed-view luminology but also does not have standardized acquisition protocols and is heavily dependent on the visual skills of the operator to acquire adequate images.

In addition to potentially providing suboptimal angiographic information, standard angiography can only provide a limited number of projections of the vascular tree despite the use of a considerable amount of contrast medium and radiation exposure. Early observational data have suggested that contrast and radiation exposure may be reduced with the use of a single anteroposterior (AP) rotation of the imaging camera while providing similar percent stenosis image information [12–14]. These findings have not been previously corroborated in any randomized study.

We have developed a high-speed rotational coronary angiographic protocol using the Philips Integris Allura monoplane system. The rotational technique uses a rapid and automated isocentric rotation of the imaging camera over a 120° arc [e.g., 60° left anterior oblique (LAO) to 60° right anterior oblique (RAO)] during a single contrast injection of the left and right coronary tree. The rotational acquisition is typically made with the addition of cranial or caudal orientation. Two rotations of the left coronary tree with cranial and caudal orientation plus a single cranial rotation of the right coronary artery comprise a complete diagnostic study. This rotational technique provides the angiographer with 360 different perspectives of the coronary tree as compared to only 6–8 viewing angles traditionally obtained with standard angiography. In this study, a prospective randomized design was used to compare the safety and clinical utility of rotational coronary angiography versus standard coronary angiography.

MATERIALS AND METHODS

Design and Patient Selection

This trial was conducted at the University of Colorado Health Sciences Center. Patient screening and enrollment occurred and informed consent was obtained in the hospitals outpatient and inpatient facilities from October 2002 to February 2003. The Colorado Institutional Review Board approved the study. Written informed consent was obtained from each patient. Inclusion criteria

were age \geq 18 years, ability and willingness to provide informed consent, and an indication for diagnostic coronary angiography. Indications for diagnostic coronary angiography included patients referred for suspected coronary artery disease following a positive functional study or prior to organ transplantation, as well as patients with acute coronary syndromes, including non-ST segment elevation myocardial infarction (MI). Exclusion criteria were pregnant females, patients with serum creatinine \geq 1.8 mg/dl not on hemodialysis, patients with acute ST segment elevation MI, prior coronary artery bypass surgery, or a known hypersensitivity to contrast media that had been previously unresponsive to pretreatment. Patients were not excluded based on weight, body habitus, or a previous history of difficult angiographic imaging.

Angiographic Studies

Fifty-six patients undergoing coronary angiography were enrolled in this study. Twenty-eight patients were randomized to standard angiography and 28 patients were randomized to rotational angiography. We evaluated patients in both the standard and rotational arm of the study using a ceiling-mounted Philips Integris Allura 12" monoplane system. All catheterization laboratory operators were board-certified invasive or interventional cardiologists with varying experience with rotational angiography. Patients receiving either standard or rotational angiography were positioned, prepared, and draped in typical fashion for a diagnostic coronary angiogram. The standard angiography protocol consisted of four images of the left coronary artery (LCA) using the traditional four gantry angles (LAO cranial, LAO caudal, RAO cranial, and RAO caudal views) and two different projections of the right coronary artery (RCA) (LAO, RAO, or AP cranial views). The specific gantry angles chosen and the magnification settings were per the operator's discretion. The intent of the protocol was to approximate current practice in the cardiac catheterization laboratory. Positioning of the image intensifier and table panning were done by the primary operator. The rotational angiography protocol consisted of three rolls or automated acquisition trajectories (Fig. 1). Two 120° rotations (60° RAO to 60° LAO) were performed using both a 25° cranial and 25° caudal tilt during image acquisition of the LCA. A single 120° rotation (60° RAO to 60° LAO) with a 25° cranial orientation was performed during image acquisition of the RCA. Each 120° acquisition was completed in 4 s. Prior to image acquisition in the rotational angiography protocol, the patient's heart was isocentered under the image intensifier by fluoroscopy in the anteroposterior and left lateral positions. Additional rotational test runs were not needed in the rotational angiography protocol. Once either the standard or rotational protocol had been completed, additional images could be taken

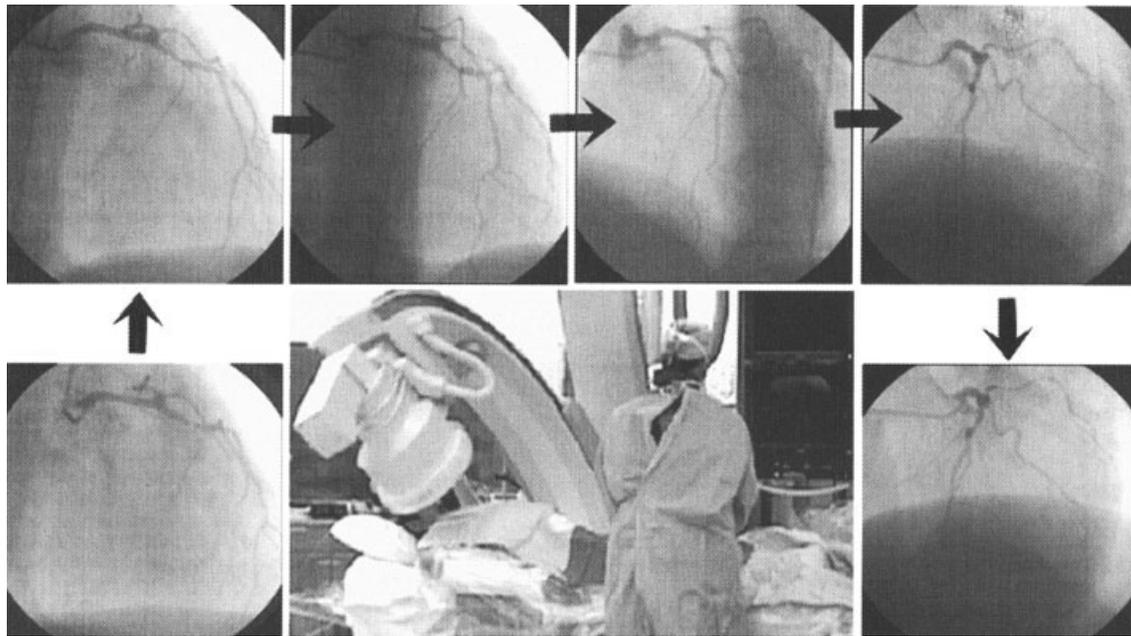


Fig. 1. Rotational coronary angiography is shown with a series of six still images of the left coronary artery selected from a rotational acquisition that started at 60° RAO with 25° cranial angulation (lower left) and ended at 60° LAO with 25° cranial angulation (lower right). Note the ability to evaluate the left main

artery and the varying degrees of foreshortening. The narrowing in the proximal left anterior descending can be well characterized from these 120 different perspectives acquired with one 8 cc contrast injection, as opposed to the 4 perspectives in the standard approach. Note the 9" field of view.

per the attending physician's discretion in order to supplement the diagnostic information obtained from the protocol images. Protocol images plus any additional images were included in the final data analysis.

Data Collection and Endpoints

Patient demographics, risk factors, and serum creatinine were collected in a prospective standardized manner before diagnostic testing. The primary endpoint of the study was patient safety (total contrast and radiation dose). The secondary endpoints of the study were operator safety (radiation exposure), time to complete a suitable angiographic study, and the clinical utility of rotational angiography using the number of additional image acquisitions needed above the protocol as an index of the adequacy or lack of adequacy of the rotational acquisition technique.

The angiographic procedure was timed from the point of catheter engagement in the coronary ostium to the determination by the attending cardiologist that a complete diagnostic study had been completed. The procedure time included the time needed to complete and review the angiograms but excluded the time needed to engage either the left or right coronary ostia or any time taken to perform noncoronary angiography. Radiation dosimeters (Landauer) specific to each study arm were used to determine cumulative operator and staff radiation

exposure. Attending physician (assistant), cardiology fellow (primary operator), and float nurse radiation dosimeters were placed outside of the thyroid collar and under the lead apron at the waist level at the time of the first coronary engagement. The radiation dosimeters were removed at the completion of the coronary angiography as determined by the attending physician. During all standard or rotational image acquisitions, operators were shielded using a ceiling-mounted radiation shield (Mavig PTZ 6290/6272). Fluoroscopy, cineangiography, and total radiation dose were recorded from the Philips Integris Allura system. Radiation dose to the patient and operators in this study reflects only radiation use during coronary angiography. This included fluoroscopy radiation dose needed to set up coronary image acquisition and excluded fluoroscopy used for catheter engagement in the coronary ostia. Coronary contrast media utilization was carefully recorded. This included contrast media used to acquire protocol and additional cineangiograms as well as any contrast media used to set up cineangiographic image acquisitions. The number of additional image acquisitions needed to complete an adequate diagnostic study was also recorded. Additional image acquisitions could either be fixed-view standard acquisitions, rotational acquisitions, or manual hybrid rotational acquisitions per the operator's discretion.

TABLE I. Baseline Clinical Characteristics by Group*

Characteristic	Standard (n = 28)	Rotational (n = 28)	P
Mean age (years)	59.5 (25–86)	57.9 (23–86)	0.66
Weight (kg)	83.6 (48–115)	79.6 (50–109)	0.40
Height (inches)	67.8 (62–76)	67.8 (59–76)	0.97
Male sex (%)	15 (53.6)	16 (57.1)	0.79
Diabetes (%)	8 (28.6)	7 (25.0)	0.71
Systemic hypertension (%)	13 (46.4)	16 (57.1)	0.51
Hyperlipidemia (%)	13 (46.4)	17 (60.7)	0.36
Smoking (%)	8 (28.6)	5 (17.8)	0.31
Family history of CAD (%)	8 (28.6)	10 (35.7)	0.64
Renal disease (%)	2 (7.1)	4 (14.3)	0.42
Prior CAD (%)	9 (32.1)	11 (39.3)	0.65
Prior MI (%)	3 (10.7)	6 (21.4)	0.31
Serum creatinine (mg/dl)	1.1	1.1	0.83

* $P < 0.05$ between each group. Data are presented as the mean value, range, and/or number (%) of patients. Renal disease is defined as a serum creatinine ≥ 1.3 mg/dl.

Immediately following a complete standard or rotational diagnostic study, the attending physicians were asked to respond in questionnaire format when additional angiograms were needed above those obtained in the study protocol. The reason(s) additional angiograms may have been obtained were divided into five categories: a segment of the coronary tree was not adequately displayed; the coronary segment of interest was displayed but a second view was needed to resolve a question concerning that coronary segment; magnification was needed to better visualize a coronary segment(s) of interest; intracoronary nitroglycerin was given and a repeat angiographic acquisition was needed; technical reasons such as catheter disengagement or poor coronary opacification required a repeat image acquisition.

Statistical Analysis

Data are presented as the mean value \pm SD for normally distributed data. A two-sided t -test was used to detect significant differences between groups. For all tests, a two-sided P value < 0.05 was regarded as significant. Computations were performed using the SAS system software package version 8. Statistical analysis of operator and staff radiation was not performed since the values represent actual cumulative measurements from study arm-specific dosimeters used throughout the study.

RESULTS

Clinical Characteristics

The initial goal of the trial was to enroll 100 patients with 50 patients randomized to each study arm. An interim analysis was set to be completed midway through the study enrollment period for safety monitoring and to look for early clinical significance. Because of marked differences between the two groups for the primary end-

point, the decision was made to stop the study early. Of the 56 patients enrolled, 28 had been randomized to standard angiography and 28 to rotational angiography. All patients randomized to standard or rotational angiography completed the protocol. There was no crossover or dropout in either study arm. There were no complications directly related to either the standard or rotational angiographic procedure. The baseline clinical characteristics by group are presented in Table I. There were no differences in any of the baseline characteristics between the two groups. Specifically, patient size (weight and height) and renal function were similar between the two groups.

Safety and Clinical Data

Contrast utilization in the rotational angiography group was lower than in the standard angiography group (35.6 ± 12.6 vs. 52.8 ± 10.7 ml, respectively; $P < 0.0001$). This represents a 33% reduction in contrast use in patients randomized to the rotational angiography group (Fig. 2). Total radiation exposure was also markedly reduced in the rotational angiography group (37.2 ± 13.2 vs. 53.9 ± 23.4 Gy cm^2 , respectively; $P = 0.002$). This represents a 31% reduction in total radiation exposure in patients randomized to the rotational angiography group (Fig. 3). Protocol fluoroscopy dose for rotational angiography was found to be lower than that used during standard angiography acquisition (2.4 ± 1.8 vs. 7.1 ± 6.5 Gy cm^2 , respectively; $P = 0.0008$). There was no difference in total fluoroscopy radiation dose between the two groups (5.4 ± 5.7 vs. 8.2 ± 9.4 Gy cm^2 ; $P = 0.2$). Cineangiographic radiation exposure (Fig. 4) was lower in the rotational angiography group as compared to the standard angiography group for both the protocol image acquisitions (13.9 ± 4.3 vs. 21.8 ± 9.6 Gy cm^2 , respectively; $P = 0.0003$) and the complete angiographic study (17.9 ± 7.5 vs. 23.9 ± 10.7 Gy cm^2 , respectively; $P =$

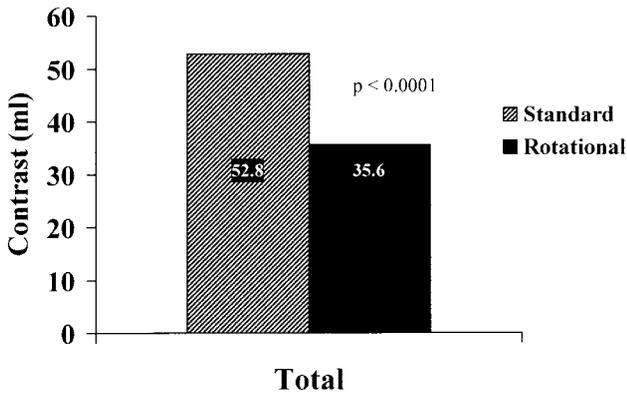


Fig. 2. Contrast utilization in milliliters for standard (n = 28) versus rotational.

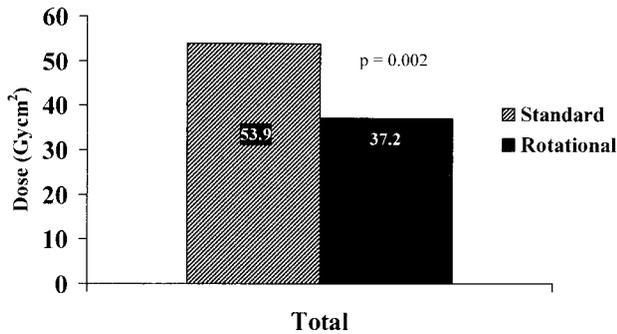


Fig. 3. Total radiation exposure in Gy cm² for standard (n = 28) versus rotational angiography (n = 28).

0.02). We found that cineangiography radiation exposure to the patients undergoing rotational angiography protocol was more standardized or predictable as compared to those undergoing the standard angiography protocol. Figure 5 demonstrates a consistent cineangiography radiation dose exposure in the rotational angiography protocol; however, patient radiation exposure during the standard angiography protocol varied widely.

Total whole-body radiation exposure or effective dose equivalent (EDE) to the primary operator was substantially lower in the rotational angiography group as compared to standard angiography (144 vs. 170 mrem, respectively). EDE values for the assistant were slightly lower in the rotational angiography group as compared to the standard angiography group (117 vs. 124 mrem, respectively). Float nurse EDE values were slightly higher in the rotational angiography group versus the standard angiography group (117 vs. 111 mrem, respectively).

To evaluate the clinical utility of rotational angiography, the total number of image acquisitions needed to complete an adequate diagnostic study was recorded. Patients randomized to the rotational angiography had a

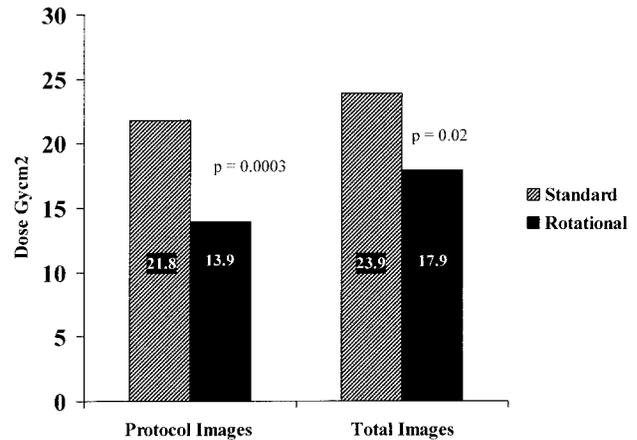


Fig. 4. Cineangiographic radiation exposure in Gy cm² for standard (n = 28) versus rotational angiography (n = 28). Protocol images represent image acquisition for the protocol only. Total images represent image acquisition for the protocol plus additional angiographic acquisitions.

41% reduction in the total number of image acquisitions (Fig. 6) needed to complete a diagnostic study (3.96 ± 1.17 vs. 6.75 ± 0.80 acquisitions, respectively; $P < 0.0001$). There was no significant difference in the need for additional image acquisitions above the protocol between the two groups (0.93 ± 1.05 vs. 0.75 ± 0.80 acquisitions, respectively; $P = 0.5$). Procedure time tended to be shorter for those randomized to rotational angiography (353.9 ± 146.7 vs. 396.8 ± 165.8 sec; $P = 0.3$).

Sixteen patients (57%) in each arm of the study required additional images above the study protocol image acquisitions. The attending physician's reason(s) for obtaining additional images are shown in Table II. The most common reason given by the attending physician for obtaining additional images during a standard angiographic study was that a segment of the coronary tree was not adequately displayed (62.5% of responses). The need for magnification was the most common reason for obtaining additional angiograms during a rotational angiographic study (18.8% of responses).

DISCUSSION

To the best of our knowledge, this is the first randomized study to compare prospectively the safety and clinical utility of rotational coronary angiography to standard coronary angiography. Our major findings are that rotational angiography exposes patients to significantly less contrast medium and radiation than standard angiography during a complete diagnostic coronary angiographic study; that rotational angiography can replace and/or complement standard angiography in the diagnosis of

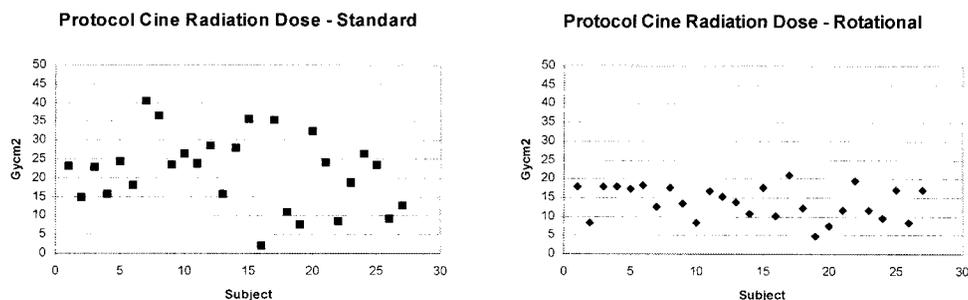


Fig. 5. Protocol cineangiographic radiation exposure in $\text{Gy}\cdot\text{cm}^2$ for each patient in the standard ($n = 28$) and rotational angiography ($n = 28$) groups.

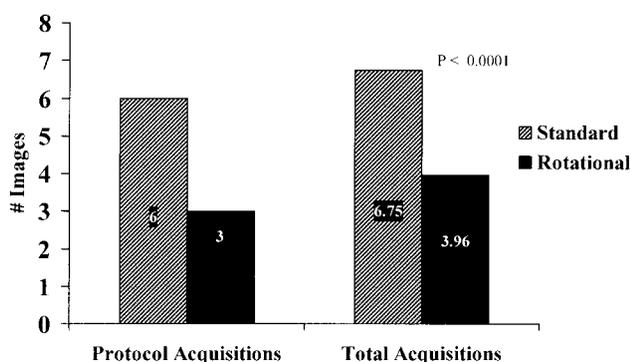


Fig. 6. Average number of cineangiographic acquisitions for the standard angiography ($n = 28$) group versus rotational angiography ($n = 28$) group. Protocol acquisitions are those image acquisitions that occurred under the study protocol only. Total acquisitions are those image acquisitions from the study protocol plus any additional images the operators felt were needed to complete a diagnostic study.

coronary artery disease; and that a complete rotational angiographic study can be performed at least as fast and efficiently as a standard angiography study (Table III).

The rotational protocol was completed in all patients with no crossover to standard angiography. Regardless of the weight or body habitus of the patients in this study, rotational angiography was successfully completed with adequate angiographic information obtained. Furthermore, a rotational test run to make sure the imaging camera trajectory was unobstructed was not required in any patients randomized to the rotational angiography group. The procedure time recorded in this study included the time needed to acquire and review the angiographic images in the cardiac catheterization laboratory. Despite varying experience in the use of the rotational angiography technique and interpretation of the rotational angiographic images among the operators, the rotational angiography protocol was completed faster than the standard angiography protocol, although this finding did not reach statistical significance.

One major advantage of rotational angiography over standard angiography is that it provides a large amount of information regarding the coronary tree with the use of less contrast and radiation. Using the rotational image acquisition protocol in this study, up to 360 projections from different angles of the coronary tree were obtained during a single angiographic study. During the standard angiographic protocol in this study, only six different projections of the coronary tree were obtained at the cost of higher contrast medium and radiation exposure to the patient. Coronary contrast medium use was reduced by one-third in the rotational angiography group. Interestingly, a marked reduction in patient radiation exposure was also seen in the rotational angiography group. The significant reductions in both contrast medium use and patient radiation exposure seen with rotational angiography may be in part explained by the marked reduction in the number of cineangiography image acquisitions needed in this group. Furthermore, fluoroscopy radiation dose needed to isocenter the camera for image acquisition in the rotational angiography protocol was 66% lower than that required to center the camera for image acquisition during the standard angiography protocol. In accordance with the “as low as reasonably achievable” (ALARA) principle of the National Council on Radiation Protection and Measurements (NCRP), the rotational angiography technique provides reduced patient radiation risk without the loss of the benefit of a complete angiographic study [15]. Our finding of substantial reductions in radiation use with rotational angiography is further emphasized by the fact that coronary angiography is the most ubiquitous invasive diagnostic procedure in the industrialized world, the frequency of patient exposure to multiple coronary angiograms is common, and the workload of operators and staff in the catheterization laboratory is increasing rapidly.

With the image intensifier high off the chest of the patient during rotational image acquisition, the rotational nature of the acquisition, and the challenges concerning shielding, we had anticipated that the operator and assis-

TABLE II. Primary Operator’s Reason(s) for Additional Image Acquisition(s) in the Standard Versus Rotational Coronary Angiography Groups

Reason(s) for additional image acquisition(s)	Standard (n = 16) ^a	Rotational (n = 16)
Coronary segment not displayed adequately	10 (62.5%)	3 (18.8%)
A second view of the coronary segment needed	4 (25%)	6 (37.5%)
Magnification needed	0 (0.0%)	9 (56.3%)
Postintracoronary nitroglycerin	1 (6.3%)	1 (6.3%)
Technical	2 (12.5%)	4 (25%)

^aValues represent the number of patients in each group who received additional angiograms.

TABLE III. Advantages and Disadvantages of Rotational Versus Standard Coronary Angiography

Advantages	
Reduces radiation exposure to the patient and all personnel	
Reduces contrast dose to the patient	
Provides additional perspectives of coronary artery tree, especially important for ostial, bifurcation, and very eccentric lesions	
Produces a 3D visual effect helping operator’s assessment of branching patterns	
Reduces the reliance on the operator’s skills to find optimal views	
Allows standardization of images acquisition protocols	
Images are internally calibrated to allow QCA without external calibration objects	
Disadvantages	
No table panning during image acquisition is possible so that larger field of view may be needed to keep entire coronary tree in all images	
Cannot be performed on older angiographic systems without rotational capabilities	
Requires operator and staff to learn proper isocentering technique	
Operator must learn to review angiographic runs with a constantly changing perspective	

tant radiation exposure would have been higher in the rotational angiography group than in the standard angiography group. To the contrary, radiation dosimeter data revealed that rotational angiography resulted in less effective whole-body radiation exposure to the operator and assistant when compared with standard angiography. Float nurse radiation exposure was slightly higher in the rotational angiography group; however, this data may be a less reliable measure since nurses were at varying distances from the radiation source during procedures and were also allowed to leave the cardiac catheterization suite if technical or patient care matters necessitated this.

The adequacy of the rotational angiographic technique in providing sufficient angiographic information during diagnostic coronary angiography was tested by determining the need for additional image acquisitions above either the standard or rotational protocols. We found that there was no significant difference in the need for additional image acquisitions between the two groups; however, there was a substantial reduction in the total number of cinangiographic image acquisitions with rotational angiography. The finding that additional images were

needed no more frequently with rotational angiography than standard angiography suggests that the rotational angiography protocol used in this study can complement, or in many cases replace, the standard angiographic technique commonly used in diagnostic coronary angiography today.

Attending physician decisions for the need for additional image acquisitions were enlightening. The need for additional angiographic images in the standard group may reflect the frequency of vessel overlap and foreshortening, which is not fully appreciated during standard angiography. The need for a second view of a coronary segment was more evenly distributed between the two groups; however, this response was seen more frequently in the rotational group. One explanation for this may be that more cranial or caudal orientation was needed in some patients during the set rotational protocol. In the rotational group, attending physicians felt that they needed to magnify on an area of interest to evaluate a coronary segment of interest. In the near future, when flat detector imaging systems become widely available, the need for magnification might not require additional image acquisitions since digital magnification alone will be sufficient. This will likely translate into even further improvements in the safety and clinical utility of rotational coronary angiography.

Rotational angiography may actually provide more information regarding the coronary tree than standard angiography. Future studies evaluating the image content of rotational angiography versus standard angiography are currently underway at our institution. Anecdotally, we believe that rotational coronary angiography is particularly useful in identifying and understanding the characteristics of lesions at bifurcations and ostia as well as very eccentric lesions in all locations. Standard views may miss these types of lesions and operator skill is particularly important in developing optimal views that allow characterization of these lesions.

Rotational coronary angiography reduces but does not eliminate the reliance on the imaging skills of the operator. The operator must still interpret the images, choose the perspectives allowing diagnosis and characterization

of abnormalities, and decide if additional image acquisitions are needed.

High-speed rotational angiography is a newly available angiographic imaging modality that improves the safety of diagnostic coronary angiography by reducing the amount of radiation and contrast media exposure to patients and radiation exposure to the operators. Rotational coronary angiography provides a rapid, complete, standardized, and, although not discussed here, less operator-dependent angiographic study, which can complement and/or replace standard angiography in patients undergoing evaluation for coronary artery disease.

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