Randomized Study of the Safety and Clinical Utility of Rotational vs. Standard Coronary Angiography Using a Flat-Panel Detector

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The purpose of this study was to test the hypothesis that rotational angiography improves patient safety while maintaining diagnostic accuracy for patients undergoing coronary angiography. Despite advances in angiographic technique, patients remain at risk for complications of coronary angiography, including contrast-induced nephropathy and radiation exposure. Technology has been developed to perform coronary angiography with active rotation of the imaging system that may reduce the quantity of contrast and radiation to which the patient is exposed. Fifty patients undergoing diagnostic cardiac catheterization were randomized to either standard vs. rotational angiography of the coronary arteries using a prespecified protocol with a flat-panel single-plane imaging system. We measured the quantity of radiographic contrast utilized and radiation exposure. Using an intention-to-treat analysis, there was a 40% reduction (24 ± 5 vs. 40 ± 10 ml; $P < 0.0001$) in contrast utilization in the rotational group compared to the standard group. Neither radiation exposure (35 ± 14 vs. 30 ± 20 Gycm^2; $P = 0.35$), fluoroscopic time (44 ± 33 vs. 44 ± 40 sec; $P = 0.99$), nor procedure time (249 ± 137 vs. 214 ± 79 sec; $P = 0.26$) differed, although significant intraoperator variability was noted for both standard and rotational angiography. The radiation exposure using this flat-panel system is significantly lower than prior reports that used an image intensifier system. Rotational coronary angiography has the potential to improve patient safety by markedly reducing radiographic contrast exposure while maintaining comparable diagnostic accuracy, radiation exposure, and procedure time compared to standard coronary angiography. © 2005 Wiley-Liss, Inc.

Key words: angiography; coronary artery disease; contrast media; radiation

INTRODUCTION

Advances in equipment, technique, and radiographic contrast used for coronary angiography have markedly improved both the safety and efficacy of this test. Despite recent advances in other less invasive diagnostic modalities, selective coronary angiography remains the gold standard for the evaluation of the severity and location of atherosclerotic lesions [1]. Using conventional angiographic techniques, it is necessary to obtain angiograms in multiple projections to overcome problems of foreshortening and vessel overlap. Furthermore, coronary angiography remains an invasive procedure that exposes patients and personnel to the potential health risks from contrast and radiation exposure.

An increasingly recognized complication of angiography is radiographic contrast-induced nephropathy (CIN), which is associated with increased morbidity and mortality after cardiac procedures. The risk for CIN is associated with several patient- and procedure-related characteristics, including increased volume of contrast [2]. Angiographic techniques that limit contrast use may therefore improve patient safety. Likewise, improvements that reduce both patient and personnel exposure to radiation are desirable. While the risk to the patient of significant radiation exposure during a

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diagnostic angiogram is small, many of the adverse effects are dose-dependent and cumulative over the entire lifespan. This is potentially important as patients are increasingly undergoing repeat cardiac and other angiographic diagnostic and therapeutic procedures. Cumulative radiation exposure is of concern for physicians and staff who regularly perform coronary angiography.

Several investigators have reported on the use of a rotational technique to reduce the number of acquisitions needed to perform a full assessment of the coronary arteries [3–5]. The gantry is set to complete a rapid right-to-left anterior oblique rotation during an angiographic injection. Typically, the left coronary artery (LCA) is visualized with both cranial and caudal angulation, and the right coronary artery (RCA) with cranial angulation. Using an image intensifier imaging system, the authors concluded that there was reduced contrast utilization and radiation exposure using the rotational technique compared to standard angiography.

We sought to confirm the findings of two published randomized studies comparing standard to rotational coronary angiography. The present rotational system included three advances over prior studies: the use of a flat-panel imaging system; the height of the flat-panel detector was lowered maximally to reduce the source-to-image distance; and the first 0.5 sec of each rotational angiogram included acquisition with a fixed gantry position to allow ascertainment of coronary calcification prior to injection of contrast as well as coronary velocity with the initiation of contrast injection. We hypothesized that the use of rotational angiography would reduce contrast utilization and X-ray exposure while achieving the same level of diagnostic accuracy.

MATERIALS AND METHODS
Design and Patient Selection

This study was conducted at the University of California San Francisco (UCSF) Medical Center. Patient screening, enrollment, and consent procedures occurred between May and August 2004. Inclusion criteria included age $\geq$ 18 years and a clinical indication for diagnostic coronary angiography. Exclusion criteria included pregnancy, serum creatinine $\geq$ 2.0 mg/dL not on hemodialysis, ST segment elevation acute myocardial infarction, and prior coronary artery bypass graft surgery. All patients gave written informed consent prior to the procedure, and the protocol was approved by the UCSF Committee on Human Research. After consent, block randomization was performed to assign patients equally to standard or rotational angiography.

The total number of patients enrolled was prospectively preset at 50.

Angiographic Studies

All angiographic procedures were performed from the femoral arterial approach using a ceiling-mounted flat-panel detector monoplane system with a rotational angiographic software package (Allura Xper FD 10, Philips Medical Systems, Bothell, WA). Hand injection of up to 10 ml of contrast was used for selective coronary angiography. Procedures were performed by one of three board-certified interventional cardiologists with varying experience with rotational angiography. The normal acquisition setting was used for patients with a body surface area (BSA) < 2.15 m^2; the large setting for patients with a BSA $\geq$ 2.15 m^2. The large setting uses a different dose curve, allowing for a longer pulse width that gives a higher mA value for kV values > 80. Fluoroscopy was performed using a 0.40 mm copper and a 1.00 mm aluminum prefilter (lowest exposure setting) in all patients.

Patients assigned to standard angiography had four different projections (RAO 30° caudal 20°, RAO 5° cranial 30°, LAO 45° cranial 30°, and LAO 5° caudal 30°) for the LCA and three projections (LAO 30°, LAO 45° cranial 30°, and RAO 30°) for the RCA. All operators used a tableside automatic positioner control panel for standard angiography to ensure the same specific gantry angles. Acquisition was obtained at 15 frames per second on 10″ magnification, which allows for postacquisition digital magnification if requested by the operator. Collimation was performed according to operator preferences.

Patients assigned to rotational angiography had a total of three coronary acquisitions specified by the protocol. Prior to acquisition, the patient's heart was isocentered using fluoroscopy in the anteroposterior and left lateral positions. Two 100° rotations (RAO 50° to LAO 50°) with either a 25° cranial or 30° caudal tilt were performed for LCA acquisition. A single 100° rotation (RAO 50° to LAO 50°) with 25° cranial tilt was performed for RCA acquisition. Each rotational acquisition began with 0.5 sec in a fixed beginning RAO 50° position, then rotated to the end LAO 50° position, completing the acquisition in 4 sec and 134 frames. Standard acquisition was obtained at 15 frames per second while rotational acquisition was obtained at 30 frames per second on 10″ magnification with no collimation. Patients assigned to either standard or rotational angiography could undergo additional coronary acquisitions at the discretion of the operator.

Data Collection and Endpoints

Patient demographics, clinical characteristics, and laboratory data were collected prospectively using a standardized intake form. The primary endpoint of the study was patient safety determined by contrast and radiation dose. Secondary endpoints included time to complete a suitable angiographic study, operator radiation exposure, and the clinical utility of rotational angiography determined by the number of additional acquisitions required beyond the protocol.

For each coronary artery, the angiographic procedure was timed from the point of selective catheter engagement in the coronary ostium to the determination by the attending cardiologist that a complete diagnostic study has been completed. The procedure time included the time needed to set up, complete, and review the angiograms. Time, contrast, and radiation exposure needed to engage the coronary ostia, perform catheter exchanges, and perform noncoronary angiography were excluded from the analyses.

After left coronary ostium engagement, radiation dosimeters (Luxel+ aluminum oxide detectors; Landauer, Glenwood, IL) specific to each study arm were positioned to determine the cumulative radiation exposure. During each case, dosimeter badges were positioned on the first operator (external collar), on the second operator (external collar), and on the medication preparation table in the cardiac catheterization laboratory. The radiation badges were left in place during LCA angiography, engagement of the RCA, and RCA angiography. Fluoroscopy time and two measures of radiation dose [dose area product (DAP, Gycm^2) and air kerma (mGy)] for fluoroscopy and image acquisition were recorded from the Philips Allura Xper system after catheter engagement and until completion of the diagnostic study for each coronary artery. DAP is a measured value obtained from an ionization chamber mounted inside the collimator. Air kerma is a calculated value from uGy/mA curves generated during the tube yield calibration that predicts patient entrance dose based on ideal positioning. The number of cineangiographic image frames for each acquisition was recorded. Coronary contrast media utilization used to acquire the protocol and any additional coronary angiographic images was recorded.

Statistical Analysis

Continuous variable data are presented as mean ± standard deviation. All analyses were performed using an intention-to-treat approach. A two-sided Student's *t*-test or chi-square test was used to detect differences between standard and rotational angiography groups where appropriate. Analysis of variance was performed

TABLE I. Baseline Clinical Characteristics by Angiography Group

Characteristic	Standard (n = 25)	Rotational (n = 25)	P
Age (years)	62.0 ± 13.2	63.3 ± 9.7	0.71
Male	56%	60%	0.77
Serum creatinine (mg/dL)	1.0 ± 0.3	1.5 ± 2.1	0.39
Height (cm)	168.3 ± 14.3	170.8 ± 10.0	0.48
Weight (kg)	86.0 ± 28.0	78.5 ± 21.0	0.30
BSA (m^2)	1.9 ± 0.3	1.9 ± 0.3	0.57

to detect differences between the three operators. For all tests, a two-sided P value < 0.05 was considered significant. The Bonferroni correction was used for multiple comparisons for continuous variables. Descriptive summaries were used for radiation badges used in the study because the values represent actual cumulative measurements from study arm-specific dosimeters. Computations were performed using a statistical software package (Stata Statistical Software release 8.0; Stata, College Station, TX).

RESULTS

Clinical Characteristics

Of the 56 patients who were enrolled in the study, 50 completed the study protocol and comprised the study cohort in this report. Reasons for noncompletion of study protocol at the discretion of the physician were early termination due to poor catheter engagement (n = 1), pressure dampening (n = 1), and severe left main stenosis (n = 1). Three other patients were excluded for incomplete data acquisition.

The baseline clinical characteristics of the study patients are presented in Table I. There were no significant differences in any of the baseline characteristics between the two groups, including patient height and weight. There was no significant difference between the radiation intensity setting for patient size between the two groups. There were no complications related to either the rotational or standard angiographic procedures.

Safety Data

Contrast utilization in the rotational angiography group was 40% lower compared to the standard angiography group (24 ± 5 vs. 40 ± 10 ml, respectively; P < 0.0001; Fig. 1). Radiation exposure was not significantly different between the rotational or standard angiography groups (35 ± 14 vs. 30 ± 20 Gycm^2, respectively; P = 0.35; Fig. 2). Fluoroscopy time was not significantly different between the rotational or standard angiography groups (44 ± 33 vs. 44 ± 40 sec, respectively; P = 0.99).
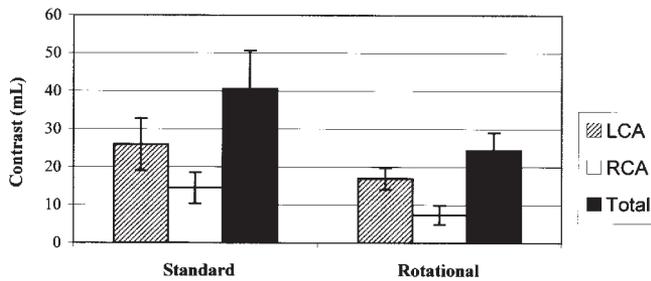
Fig. 1. Contrast utilization in milliliters for the standard angiography group (n = 25) vs. the rotational angiography group (n = 25). Contrast utilization for the total protocol, left coronary artery (LCA), and right coronary artery (RCA) acquisitions are shown (*P* < 0.0001 for each comparison).
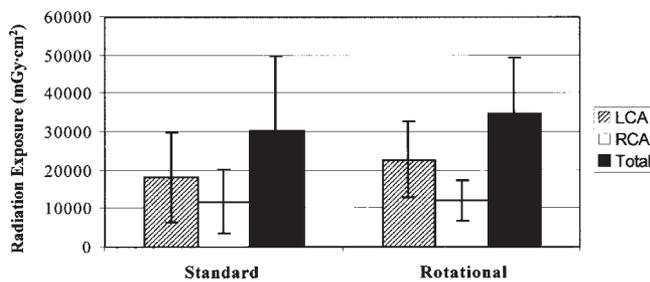

Fig. 3. Average number of cineangiographic image acquisitions for the standard angiography group (n = 25) vs. the rotational angiography group (n = 25; *P* < 0.001).

Fig. 2. Total radiation exposure in Gycm^2 for the standard angiography group (n = 25) vs. the rotational angiography group (n = 25). Radiation exposure for the total protocol (*P* = 0.35), left coronary artery (LCA; *P* = 0.16), and artery right coronary (RCA; *P* = 0.93) acquisitions are shown.

The dosimeter data represent the aggregate radiation exposure for the 25 patients in each treatment group. There were no significant differences or trends in the skin dose radiation exposure between the rotational and standard angiography groups for the primary operator (36 vs. 33 mrem, respectively), the secondary operator (17 vs. 21 mrem), and the cardiac catheterization room (24 vs. 31 mrem). Because there was no significant difference in procedure time or radiation exposure (Gycm^2) during catheter exchange after left coronary angiography and subsequent right coronary artery engagement, the total whole body radiation exposure detected by the dosimeter badges accurately reflect the radiation exposure to physicians and staff performing rotational and standard angiography.

Clinical Data

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 rotational angiography had a 56% reduction in the total number of image acquisitions (3.2 ± 0.5 vs. 7.3 ± 0.6, respectively; *P*
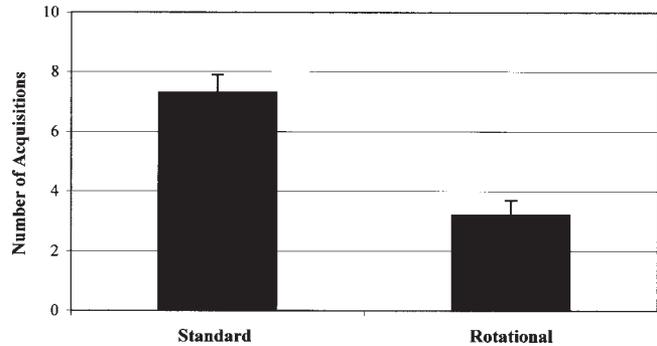
< 0.0001; Fig. 3). Despite image acquisition at 30 frames per second with rotational angiography and 15 frames per second with standard angiography, 16% fewer frames were generated in the rotational angiography group compared to the standard angiography group (405 ± 34 vs. 484 ± 104, respectively; *P* < 0.01).

There was no significant difference in the need for additional image acquisitions beyond the protocol acquisitions in the rotational and standard angiography groups (0.2 ± 0.5 vs. 0.3 ± 0.6, respectively; *P* = 0.38). Additional coronary acquisitions were obtained at the operators' discretion: a total of five additional acquisitions in four patients (16%) in the rotational angiography group, and a total of eight additional acquisitions in seven patients (28%) in the standard angiography group (*P* = 0.31). In the rotational angiography group, indications for additional images included improper isocentering (three acquisitions), catheter disengagement (n = 1), and postnitroglycerin (n = 1). In the standard angiography group, indications for additional images included better visualization using a different projection angle (n = 5), catheter disengagement (n = 2), and improper positioning (n = 1).

There was no difference in the protocol time between rotational or standard angiography groups (249 ± 137 vs. 214 ± 79 sec, respectively; *P* = 0.26). There was no difference in the time for left coronary (160 ± 110 vs. 136 ± 53 sec; *P* = 0.33) or right coronary acquisition (90 ± 60 vs. 78 ± 37 sec; *P* = 0.41) between rotational or standard angiography groups, respectively.

To assess the impact of the learning curve for rotational angiography, subgroup analysis was performed comparing early (n = 13) vs. late (n = 12) studies within each study arm. In the rotational angiography arm, early studies tended to utilize more time for coro-
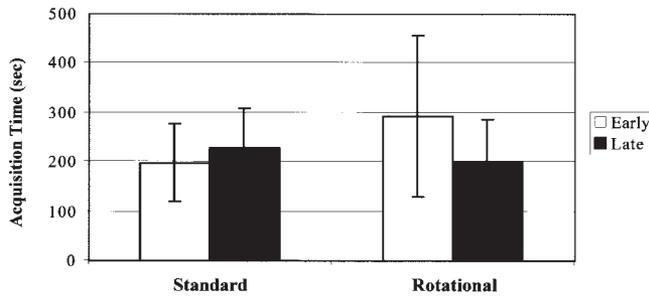
Fig. 4. Comparison of procedure time in seconds between early (n = 13) and late (n = 12) studies in the standard angiography group (n = 25; *P* = 0.34) vs. the rotational angiography group (n = 25; *P* = 0.09).

nary acquisition (293 ± 163 sec) compared to late studies (202 ± 85 late sec; *P* = 0.09; Fig. 4). Early studies also used more fluoroscopy time (53 ± 42 sec) compared to late studies (34 ± 15 sec; *P* = 0.15). In addition, all cases requiring additional image acquisitions in the rotational arm occurred during the early phase. In the standard angiography arm, there were no differences in protocol time (199 ± 79 vs. 230 ± 80 sec; *P* = 0.34), fluoroscopy time (45 ± 50 vs. 42 ± 26 sec; *P* = 0.52), or need for additional image acquisitions (0.4 ± 0.4 vs. 0.3 ± 0.2; *P* = 0.56) between early and late studies, respectively. There was no difference in contrast or radiation exposure between early and late studies within either the rotational or standard angiography arms.

Subgroup analysis by operator for the rotational and standard angiography groups is presented in Table II. There is significant interoperator variation in protocol time, radiation exposure, and fluoroscopy time in both standard and rotational angiography arms.

DISCUSSION

In this prospective randomized trial comparing the safety and clinical utility of rotational vs. standard coronary angiography, we demonstrated that rotational angiography is a safe, efficient, and clinically comparable alternative to standard angiography in the diagnosis of coronary artery disease. There was a significant reduction in contrast media utilization with the rotational technique. We also observed a learning curve with rotational angiography.

The first prospective randomized study comparing rotational angiography with standard angiography used an older angiographic system with an image intensifier (Philips Integris Allura monoplane) to study 56 patients undergoing diagnostic coronary angiography [3]. The investigators reported a 33% reduction in contrast utilization, a 28% reduction in radiation exposure,

and a trend toward shorter procedure time with rotational compared to standard coronary angiography. In a similar study design comparing rotational and standard coronary angiography in 75 patients using the General Electric flat-panel detector Innova 2000, rotational angiography resulted in a 19% reduction in contrast utilization for left coronary acquisition and no difference in contrast utilization for right coronary acquisition [4]. Rotational angiography also reduced radiation exposure by 34% and 59% for left and right coronary acquisition, respectively. Both studies found that rotational angiography is a clinically acceptable method for diagnostic coronary angiography.

Our data confirm these two prior reports that rotational coronary angiography reduces patient exposure to contrast medium. The magnitude of reduction in contrast exposure by 40% in our study is similar to the reduction reported by Maddux et al. [3] (33 percent). Kuon et al. [5] previously noted a 61% reduction in contrast exposure by rotational angiography. However, this finding may be an overestimate given their older imaging technology and small sample size (n = 15). The significant reduction in contrast medium use by rotational angiography can be explained by the marked reduction in the number of cineangiographic image acquisitions. Our study reported a 40% decrease in contrast volume utilization, providing further evidence that rotational coronary angiography is likely to minimize morbidity and mortality for patients at increased risk for CIN [5,6].

Radiation exposure in both the rotational and standard angiography arms of our study was significantly lower compared to prior studies. Maddux et al. [3] reported a mean radiation dose of 54 ± 23 Gycm^2 for standard coronary angiography with the image intensifier Philips system. Raman et al. [4] reported a mean total dose of 225 Gycm^2 with the flat-panel GE system (note that the standard deviation for total radiation for both coronary arteries was not provided). In our study, the average radiation dose with standard angiography was only 30 ± 20 Gycm^2. Radiation dose for rotational coronary angiography was also lower in our study (35 ± 14 Gycm^2) compared to Maddux et al. [3] (39 ± 19 Gycm^2) or Raman et al. [4] (102 Gycm^2).

Our finding that radiation exposure is similar between rotational and standard coronary angiography may be a result of improvements in radiation dose efficiency for standard coronary angiography compared to prior studies. The reduced radiation doses in our study may result from improvements in technology or operator technique. Average patient body surface area is similar between the studies and unlikely to account for this difference. It is noteworthy that rotational angiog-

TABLE II. Subgroup Analysis by Operator

Standard angiography				
Characteristic	Operator 1 (n = 13)	Operator 2 (n = 6)	Operator 3 (n = 6)	P
Procedure time (sec)	171 ± 40	222 ± 80	298 ± 80	0.10
Fluoroscopy time (sec)	29 ± 14	33 ± 13	84 ± 65	< 0.001
Radiation dose (Gycm^2)	24 ± 12	23 ± 8	51 ± 28	0.01
Number of acquisitions	6.8 ± 0.6	7.3 ± 0.5	8.0 ± 0.6	0.89
Rotational angiography				
Characteristic	Operator 1 (n = 17)	Operator 2 (n = 4)	Operator 3 (n = 4)	P
Procedure time (sec)	197 ± 60	322 ± 127	399 ± 248	0.001
Fluoroscopy time (sec)	32 ± 14	47 ± 17	89 ± 61	< 0.001
Radiation dose (Gycm^2)	31 ± 10	40 ± 20	47 ± 19	0.15
Number of acquisitions	3.1 ± 0.2	3.2 ± 0.5	3.7 ± 1.0	< 0.001

raphy is acquired at 30 frames per second because of the rapid gantry movement, while standard angiography was acquired at 15 frames per second in our laboratory. Despite the higher acquisition rate with rotational angiography, the radiation exposure was not different between the two strategies and fewer total angiographic frames were acquired using rotational angiography per case.

Procedure time in both rotational and standard angiography arms of our study was also less than prior studies. Whereas Maddux et al. [3] reported an average time for standard coronary angiography of 354 ± 147 sec, our average time using automatic position control with standard angiography was 214 ± 79 sec. Raman et al. [4] did not report coronary acquisition times for standard angiography, but did report a mean total time of 267 sec for rotational angiography (standard deviation not reported). Rotational coronary angiography was also performed faster in our study (249 ± 136 sec) compared to Maddux et al. [3] (397 ± 166 sec). Given that the time for rotational coronary angiography was comparable to the time for standard coronary angiography using our automatic position control, we concluded that standard and rotational angiography are both time-efficient methods of coronary angiography.

We assessed the adequacy of rotational angiographic technique in providing sufficient angiographic information during diagnostic coronary angiography by the need for additional image acquisitions above either the standard or rotational protocol. We observed that additional images were performed less frequently with rotational angiography than with standard angiography. Whereas Maddux et al. [3] previously reported that the most common reason for additional image acquisitions using rotational angiography was the need for better magnification (9 acquisitions in 16 patients), the use of a flat-panel detector for enhanced digital image magnification in our study eliminated this need. The most common reason for additional image acquisition in our rotational angiography group (16% of the 25 patients)

was improper isocentering, all of which occurred in the first half of rotational studies performed. No patients required additional coronary acquisitions because of the need for a different angiographic projection in the rotational group, while 20% of the patients in the standard angiography group required additional angiograms because of inadequate angulation.

Rotational angiography may provide more information about the coronary tree than standard angiography, particularly in understanding eccentric lesions or lesions at bifurcations or ostia [7]. Initial image content study by Raman et al. [4] showed comparable visualization of coronary anatomy between rotational and standard angiography.

Comparison between early and late studies within each angiographic strategy arm revealed the presence of a learning curve for rotational angiography in our study. The latter half of rotational studies (n = 12) were performed faster and used less fluoroscopy time compared to the early rotational studies. The total procedure and fluoroscopy time in the later rotational angiographic studies were comparable to the standard angiography group, which did not exhibit a learning curve regarding changes in procedure or fluoroscopy time.

Limitations of our study are the small study number and variability in procedure time, radiation exposure, and fluoroscopy time between the three operators performing rotational and standard coronary angiography. Because of the lack of differences in procedure time and radiation exposure in the later rotational cases and the standard angiography group, we felt that expanding this study's subject number would be unlikely to change the overall results. Interoperator variability did not impact our results because the variability was present in both arms of the study and the relatively small numbers of studies performed by operators 2 and 3 were similarly distributed between rotational and standard arms. The observed interoperator variability

does highlight the importance of ongoing physician training to optimize patient safety during coronary angiography [8].

In conclusion, rotational angiography is a safe and efficient method of diagnostic coronary angiography that provides comparable clinical information to standard coronary angiography. Rotational angiography is associated with a significant reduction in contrast medium exposure, which may provide benefit to those patients at increased risk for CIN. Rotational and standard angiography have comparable levels of radiation exposure and procedure time. The radiation exposure from either rotational or standard angiography using this flat-panel system is significantly lower than prior reports that used an image intensifier system. Additional prospective studies evaluating image content are needed to determine whether rotational coronary angiography can replace standard angiography in the diagnosis of coronary artery disease. Studies involving three-dimensional coronary artery reconstruction derived from rotational angiography are underway.

ACKNOWLEDGMENTS

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