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RANDOMIZED TRIAL

A Randomized Trial Comparing Dual Axis Rotational Versus Conventional Coronary Angiography in a Population with a High Prevalence of Coronary Artery Disease

RAFAEL S. O. GIUBERTI, M.D.,[1,2] ADRIANO CAIXETA, M.D., PH.D.,[2]
ANTÔNIO C. CARVALHO, M.D., PH.D.,[2] MILTON M. SOARES, M.D., PH.D.,[1]
ERLON O. ABREU-SILVA, M.D.,[1] JOSÉ O. MEDINA PESTANA, M.D., PH.D.,[1]
HÉLIO T. SILVA JÚNIOR, M.D., PH.D.,[1] MARIA LÚCIA VAZ, M.D., PH.D.,[1]
PHILIPPE GÉNÉREUX, M.D.,[3,4] and ROSLEY W. A. FERNANDES, M.D., PH.D.[1]

From the [1]Hospital do Rim; [2]Hospital São Paulo, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, Brazil; [3]Columbia University Medical Center and the Cardiovascular Research Foundation, New York, New York; and [4]Hôspital du Sacré-Cœur de Montréal, Montréal, Québec, Canada

Objectives: *To compare the safety, radiation dose, and contrast volume between dual axis rotational coronary angiography (DARCA) and conventional coronary angiography (CCA).*
Background: *CCA is performed in multiple, predefined stationary views, at different angulations around the patient, for both the left and right coronary arteries. DARCA (AlluraXperSwing™, Philips, the Netherlands) involves a pre-set rotation of the C-arm around the patient and allows for the visualization of each coronary artery in different views, using a single automatic pump contrast injection.*
Methods: *From November 2012 to February 2013, 201 patients were randomly assigned to either CCA (n = 100) or DARCA (n = 101). Exclusion criteria included acute coronary syndrome (ACS), prior PCI or CABG. CCAs were performed in 4 acquisition runs for the left coronary artery and 2 to 3 acquisition runs for the right coronary artery, whereas DARCAs were performed in a single run for each coronary artery.*
Results: *Baseline demographics and clinical characteristics were similar for both groups. The overall prevalence of CAD was 77.6%. The DARCA group had a significant reduction in the amount of contrast, 60 ml (IQR: 52.5–71.5 ml) versus 76 ml (IQR: 68–87 ml), $P < 0.0001$; and radiation dose by Air Kerma, 269.5 mGy (IQR: 176–450.5) versus 542.1 mGy (IQR: 370.7–720.8), $P < 0.0001$. There were fewer patients requiring additional projections in the DARCA group: 54.0% versus 75.0%; $P = 0.002$.*
Conclusions: *In a population with a high prevalence of CAD, DARCA was safe and resulted in a significant decrease in contrast volume and radiation dose.* (J Interven Cardiol 2014;9999:1–9)

Introduction

Conventional coronary angiography (CCA) remains the gold standard diagnostic exam in patients with coronary artery disease (CAD). However, there are limitations to this technique due to vessel overlap, foreshortening, and unappreciated tortuosity. This is especially true in the setting of complex coronary anatomy.[1,2] One explanation for the diagnostic inaccuracy of angiographic exams has been the use of relatively few static or fixed acquisitions, usually between 4 and 6 views of the left coronary tree and 2 and 3 views of the right coronary tree.[3] Indeed, these standard angiographic acquisitions are adapted for each case, according to anatomical findings, and influenced

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Address for reprints: Adriano Caixeta, M.D., Ph.D., Department of Interventional Cardiology, Escola Paulista de Medicina, Av. Napoleão de Barros, 715, São Paulo 04024-002, Brazil. Fax: +55-11-55764014; e-mail: acaixeta@me.com

by the operator's personal experience. Most importantly, they may be limited by time, safety, and cost. Even when acquiring multiple views, the gap between adjacent projections and potential deviation from the optimal angle of observation has been noted to range from 30° to greater than 90°, which can lead to a gross underestimation of lesion severity.[4,5] In addition, the operator's attempts to determine the best views is time consuming and usually leads to higher amounts of contrast medium and radiation doses.

Dual-axis rotational coronary angiography (DARCA) has been introduced to potentially overcome these limitations. DARCA consists of a novel type of rotational angiography (RA) with simultaneous cranial-to-caudal and left anterior oblique-to-right anterior oblique (LAO-to-RAO) acquisition arcs, so each coronary (left coronary artery [LCA] or right coronary artery [RCA]) can be completely evaluated using only 1 for a total of 2 acquisitions, instead of the 3 required with single-axis rotational coronary angiography. The exact pathway that the gantry follows in DARCA is determined by using 3-dimensional models generated from RA to obtain images on a trajectory specifically designed to reduce vessel foreshortening.

Previous studies already have shown a reduction in radiation dose and contrast volume using DARCA,[6–9] but these results have not been replicated in specific studies in a population with a high prevalence of CAD. Therefore, we sought to compare the safety, radiation dose, contrast volume, and procedure time between the DARCA and CCA techniques in a setting characterized by a high prevalence of CAD.

Methods

Study Design. The present study is an all-comers, prospective, randomized, open-label trial that includes patients older than 18 referred to elective coronary angiography between November 2012 and February 2013. The exclusion criteria were: acute coronary syndrome (ACS), prior coronary artery bypass graft (CABG), or prior percutaneous coronary intervention (PCI). Patients were randomized in a 1:1 ratio by order of inclusion for CCA or DARCA.

Angiography Protocol. All angiographic procedures were performed by femoral approach and the Allura Xper FD 10 digital X-ray system (XperSwing™ Philips Healthcare, Eindhoven, The Netherlands) was used for DARCA. A hypo-osmolar contrast agent was injected manually for static projections and by an automatic injection pump for rotational projections through a 6-French catheter. CCAs were performed in 4 acquisition runs for the LCA (RAO-caudal, RAO-cranial, LAO-cranial, and LAO-caudal) and in 2 to 3 acquisition runs for the RCA (LAO, RAO, and LAO-cranial, if dominant). DARCAs were performed in a single run for each coronary artery. Following appropriate coronary catheterization, RA requires finding the isocenter using fluoroscopy in the anteroposterior (AP) position by table panning and then in the left lateral position (LAO 90°) by elevating or lowering the table. During isocentering, a contrast agent flush was used to confirm that the heart of the patient and coronary tree were well centered. DARCA acquisition is automated, that is, the rotating C-arm follows a pre-established trajectory. We used Swing LCA cranial 40° 5.8 seconds or Swing LCA cranial 35° 5.8 seconds in obese patients for the LCA and the Swing RAO caudal-LAO cranial 4.1 seconds for the RCA. Figure 1 shows the detector trajectory during acquisition in both coronaries. Prior studies did not show any hemodynamic disturbance or adverse effect related to this type of prolonged injection.[10] Once the appropriate mode was selected, the gantry was set to the pre-specified end and start positions for the respective coronary tree without fluoroscopy. During this period, the arc made the programmed path in the safe mode, interrupting its path if it encountered obstacles such as the patient's arms, intravenous infusion equipment, or surgical field. All DARCA acquisitions were performed by coordinating between the automatic pump and the gantry motion; the contrast flow rate was 4 ml/s for a total of 24 ml for the LCA and 12 ml for the RCA. The use of this adjusted protocol of prolonged and higher volume of contrast injection than previously reported—and recommended by the manufacturer—during DARCA acquisitions is most likely explained by an increased resistance to intracoronary flow found in this particular subset of patients (Table 1; e.g., high prevalence of chronic kidney disease on dialysis and severe hypertension). However, there were no adverse effects associated with this rate of contrast delivery. The pressure setting on the automatic pump was 400 psi. DARCA acquisition was obtained at 30 frames per second on 25 cm magnification (Fig. 2), whereas CCA acquisition was obtained at 15 frames per second on 20 cm magnification.

Four experienced operators participated in the study and were encouraged to not modify their usual

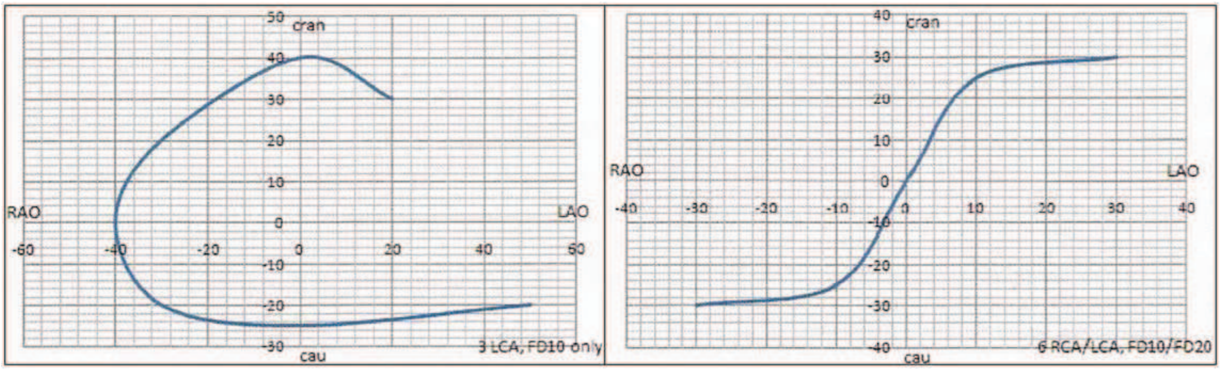

Figure 1. Detector trajectory of the left (left) and the right coronary artery (right) during rotational angiography. Courtesy by Philips, Eindhoven, the Netherlands.

Table 1. Baseline Clinical Characteristics according to CCA and DARCA Groups

	CCA (n = 100)	DARCA (n = 101)	P-Value
Age (years)	57 (51–63)	55 (47–62)	0.07
Male	60 (60.0)	64 (63.4)	0.62
Weight (kg)	69.5 (61.2–77)	70 (62.5–80)	0.61
Height (cm)	165 (159.2–170)	165 (160–170.5)	0.32
BMI (kg/m^2)	25.1 (23–27.8)	25.2 (22.2–29)	0.90
Thoracic thickness (cm)	24 (22–26)	24 (22–26)	0.79
Hypertension	88 (88.0)	97 (96.0)	0.04
Diabetes	70 (70.0)	71 (70.9)	0.91
Non-insulin dependent	23 (23.0)	21 (20.8)	
Insulin dependent	47 (47.0)	50 (49.5)	
Hyperlipidemia	58 (58.0)	48 (47.5)	0.13
Family history of CAD	2 (2.0)	3 (3.0)	0.65
Peripheral vascular disease	9 (9.0)	7 (6.9)	0.61
Previous CAD	8 (8.0)	6 (5.9)	0.56
Symptoms			0.59
Asymptomatic	68 (68.0)	62 (61.4)	
Stable angina Class 1 or 2	28 (28.0)	35 (34.7)	
Stable angina Class 3 or 4	4 (4.0)	4 (4.0)	
Smoking			
Never	59 (59.0)	62 (61.4)	0.87
Previous	34 (34.0)	31 (30.7)	
Current	7 (7.0)	8 (7.9)	
Prior myocardial infarction	0 (0.0)	1 (0.5)	0.99
Prior stroke	7 (7)	3 (3.0)	0.21
Dialysis	82 (82.0)	82 (81.2)	0.88
Time on dialysis (months)	14.5 (7–30)	18 (7–41)	0.59
Prior kidney transplantation	14 (14.0)	13 (12.8)	0.81
CAD	83 (83.0)	74 (73.2)	0.09
Pattern of CAD (>50%)	62 (62.0)	55 (54,5)	0.53
Single-vessel disease	25 (25.0)	24 (23.7)	
Two-vessel disease	16 (16.0)	17 (16.8)	
Three-vessel disease	21 (21.0)	14 (13.9)	
Left-main	7 (7.0)	5 (4.9)	0.56
End-diastolic volume of the left ventricle	90.5 (70.3–115.6)	93.4 (69–120.7)	0.74
Left ventricular dysfunction	13 (13.0)	17 (16.8)	0.81
Right coronary dominance pattern	86 (86.0)	89 (88.1)	0.65

CCA, conventional coronary angiography; DARCA, dual-axis rotational coronary angiography; CAD, coronary artery disease; BMI, body mass index. Values are presented as number (%) or median (25–75% interquartile). P-values: CCA group versus DARCA group.

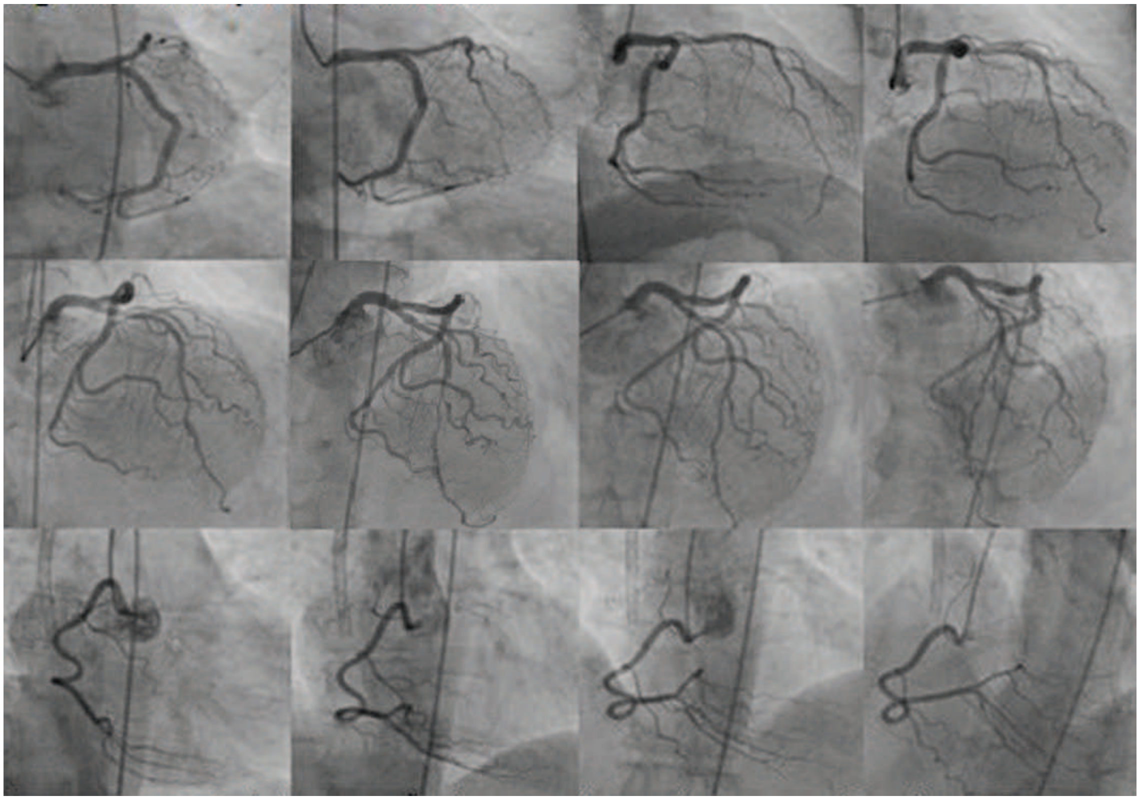

Figure 2. Examples of rotational coronary angiographies. The first and second rows of images on the top show a rotational spin of the left coronary artery with a dominant left coronary artery. The third row depicts an example of rotational spin of a tortuous right coronary artery.

coronary angiography routines. Additional projections were allowed at the operator's discretion to better define the coronary anatomy after the protocol-mandated projections. If severe left main stenosis was detected by fluoroscopy or pressure dampening, the use of DARCA was also at the discretion of the operator. Patients with total occlusion or poorly developed RCA were excluded for RA. The flat detector distance to the patient was minimized in conventional procedures, as is the norm, but in DARCA procedures, the default distance was adopted as the maximum distance from the patient. Fluoroscopy was performed in the lowest level of the 3 available modes. Automatic tube adjustments for KvP/mA were used for all procedures.

Data Collection and Study Endpoints. The procedure time in minutes was counted from the first catheterization of the LCA to the last view of RCA including the time spending during isocenter procedure for both coronaries. A timer has been set by the operator on the Allura Xper FD 10 touch screen. The radiation dose was calculated by dose-area product ($Gycm^2$), fluoroscopy time (minutes), and cumulative AirKerma (mGy). The radiation dose, contrast volume, and time required for achievement of any ventriculography or aortography were not considered for analysis.

Statistical Analysis. Categorical variables were expressed as numbers or percentages and compared using chi-squared statistics or a Fisher's exact test, as appropriate. The quantitative variables were expressed as a mean (and standard deviation) or median (range 25–75%). The sample distribution was evaluated by the Kolmogorov–Smirnov test, using the Student's *t*-test (normal distribution) or nonparametric Wilcoxon and Mann-Whitney tests (non-normal distribution) for the analysis. We estimated the sample size based on previous studies (7, 9, 6); that with a power of 80%, level of significance of 5%, an effect size of 35% reduction in radiation dose (DARCA vs. CCA), and 5% of loss of information, 100 subjects would be necessary in each group. Subgroup analyses were performed to assess radiation dose and contrast media volume occurring in different patient subsets by analyzing subtractions at different percentiles and linear regression. For all comparisons, a P value of <0.05 (2-sided) was considered statistically significant. Statistical analysis was performed by SPSS 21.0 software for Windows. The study was approved by the respective ethics committees at our hospital and signed informed consent was obtained from all patients.

Results

All of the 201 patients who were enrolled in the study completed the protocol, 101 patients in the DARCA group and 100 patients in the CCA group (Fig. 3). Baseline demographics and clinical characteristics were similar for both groups, except for a higher prevalence of hypertension in the DARCA group (Table 1). Our sample shows a high prevalence of chronic kidney disease on dialysis (81.6%), diabetes (70.0%), and severe hypertension (92.0%), with an overall 78% incidence of CAD.

Compared with the CCA group, the total contrast volume decreased by 21% and the total radiation exposure was reduced by 51.3% in the DARCA group (Table 2). Of note, these findings remained consistent across all patient subgroups, as we can see in Figures 4 and 5. In addition, with regard to the total radiation dose, there was a trend suggesting incremental benefits with the use of DARCA compared to CCA with increased body mass index (BMI; Fig. 6). The percentage of patients requiring additional acquisitions was higher in the CCA group (75.0%) than in the DARCA group (54.4%); however, there was no difference between groups when considering the mean of extra views per patient (1.21 in CCA vs. 1.25 in DARCA; $P = 0.44$). Compared with CCA, DARCA required a longer procedure time of 1 minute and 10 seconds, an increase of 15.6%. At the operator's discretion, 10 rotations of the RCA were not performed, 5 due to chronic total occlusion, 3 because of unstable catheter engagement of the RCA, and 2 because of non-dominant RCA. One rotation of the LCA was aborted due to severe left main stenosis and pressure dampening. Two patients in the DARCA group and 1 patient in the conventional group experienced nausea. One patient in each group had developed allergic symptoms characterized by an itchy cutaneous rash. There was 1 episode of asymptomatic self-limited bradycardia in the CCA group. There were no other procedure-associated symptoms observed or reported after injection in either group.

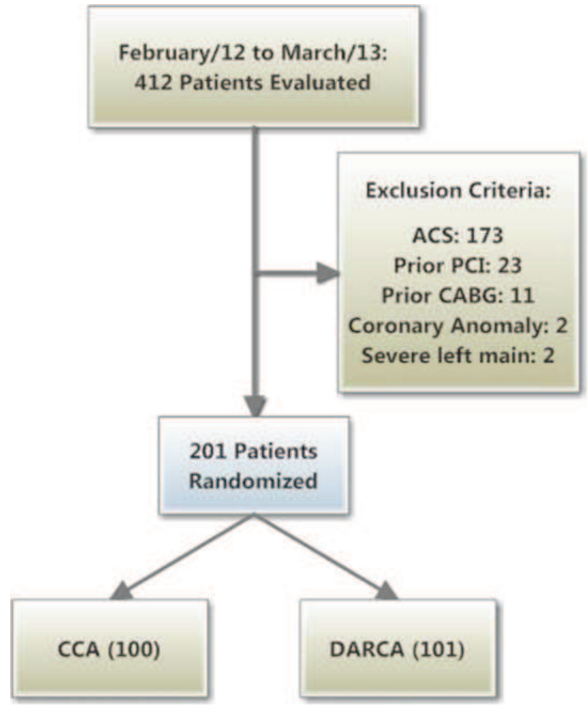

Figure 3. Flow chart of the present study. ACS, acute coronary syndromes; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; DARCA, dual-axis rotational coronary angiography; CCA, conventional coronary angiography.

Discussion

The principal findings of the present study comparing DARCA and CCA are the following: (1) the exposure to contrast agents and radiation is lower in DARCA than in CCA; (2) these advantages are apparent in all subgroups evaluated; and (3) the reduction in radiation dose is directly proportional to the patient's BMI.

Our institution is a major kidney transplant center in Brazil, explaining the high prevalence of chronic kidney disease on dialysis (81.6%), diabetes (70.0%), and severe hypertension (92.0%) among the studied population. This demographic peculiarity in our patients having an increased resistance to intracoronary flow of contrast led us to modify the injection protocol suggested by the manufacturer from LCA 15 ml at 2.5 ml/s to 24 ml at 4 ml/s and for the RCA from 9 ml at

Table 2. Radiation Dose, Contrast Volume and Procedure Characteristics According to CCA and DARCA Groups

	CCA	DARCA	P-Value
Contrast use (ml)	76 (68–87)	60 (52.5–71.5)	<0.0001
Radiation exposure			
DAP (Gycm^2)	30 (20.9–37.4)	20 (13.2–29.2)	<0.0001
Kerma (mGy)	542.1 (370.7–720.8)	269.5 (176.2–450.5)	<0.0001
Fluoroscopy time (min)	2′45″ (2′12″-3′34″)	3′01″ (2′30″-3′49″)	0.04
Procedure time (min)	6′20″ (5′06″-8′23″)	7′30″ (5′56″-8′57″)	0.008
Extra views (n)			
Mean	1.21 (0.5–2)	1.25 (0–2)	0.44
Patients	75 (75)	55 (54.4)	0.002
Total views (n)	8 (7–9)	3 (2–5)	<0.0001

DARCA, dual-axis rotational coronary angiography; CCA, conventional coronary angiography; DAP, dose-area product. Values are presented as median ± IQR 25–75%. P-values: DARCA group versus CCA group.

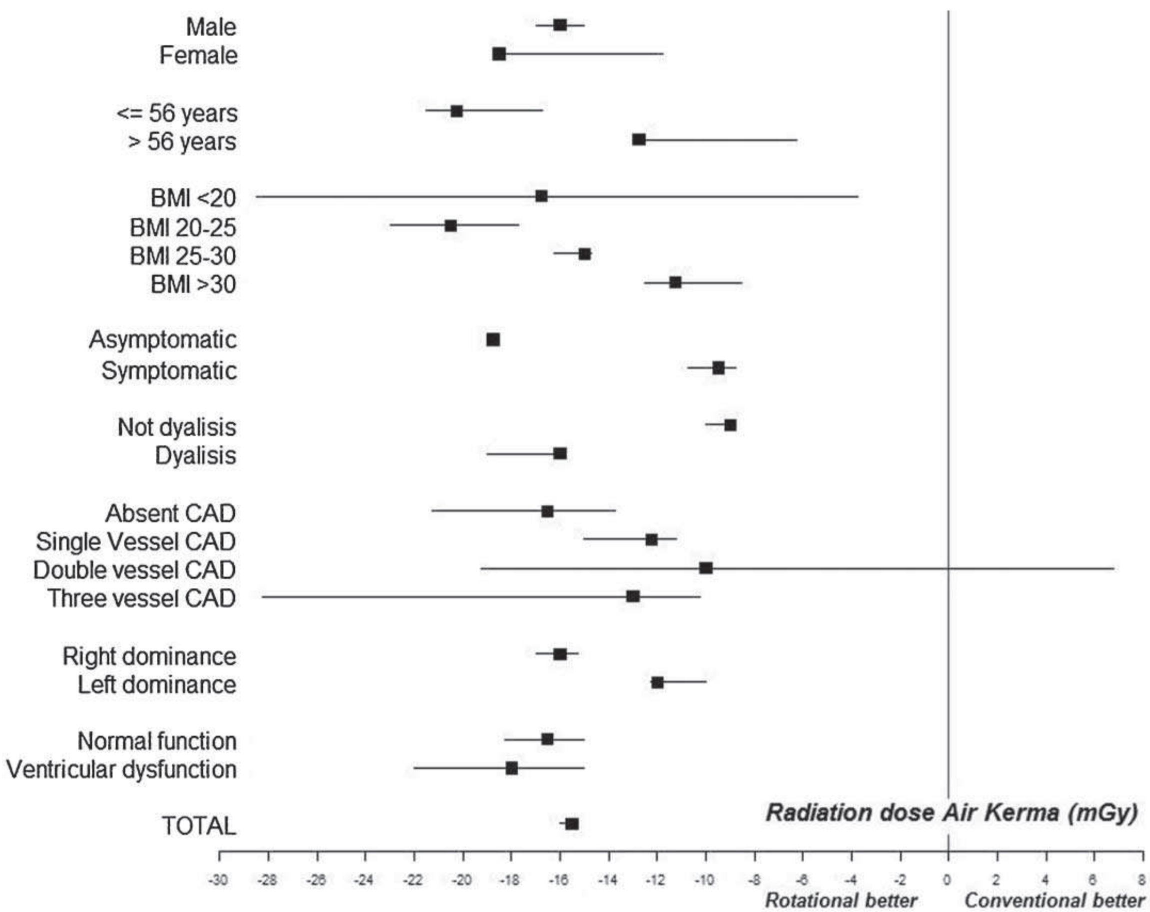

Figure 4. Subgroup analysis showing differences in radiation dose between the rotational and conventional coronary angiography groups for the 25th, 50th, and 75th percentiles. BMI, body mass index; CAD, coronary artery disease.

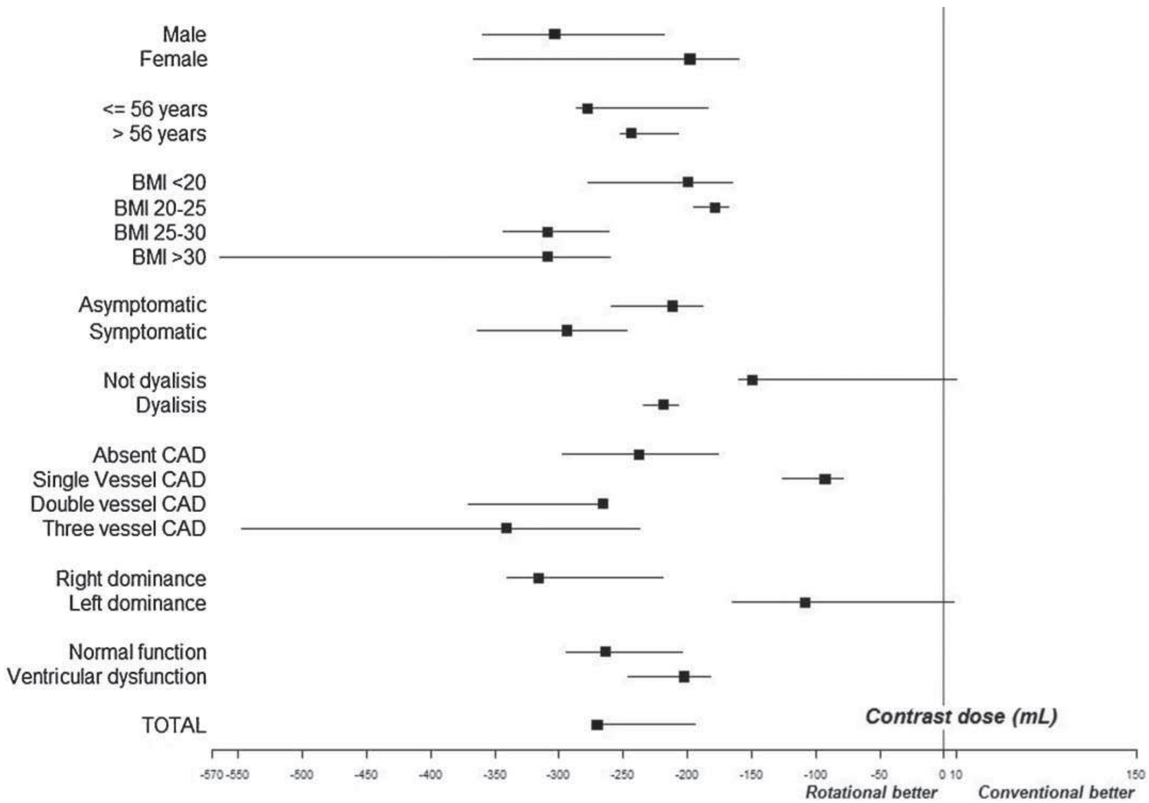

Figure 5. Subgroup analysis showing differences in contrast volume between the rotational and conventional coronary angiography groups for the 25th, 50th, and 75th percentiles. BMI, body mass index; CAD, coronary artery disease.

1.5 ml/s to 12 ml at 4 ml/s, in addition to using 6-F transfemoral sheaths. Even so, a significant 21% reduction in the amount of contrast medium used was noted in the DARCA group, which represents a smaller decrease than that seen in recent studies, ranging from 41% to 49%.[7,6,9,11] The correlation between contrast media volume, the risk of contrast-induced acute kidney injury (AKI), and impact on the prognosis of patients has been documented in several studies.[12–14] Thus, minimization of contrast volume is of paramount importance to prevent contrast-induced AKI in patients undergoing angiography.

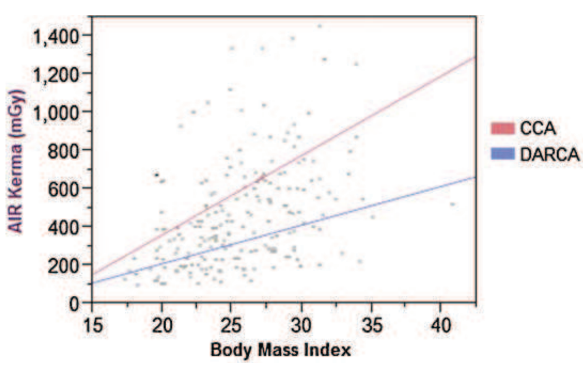

Figure 6. Bivariate behavior of AIR Kerma dose according to body mass index and the type of angiography. DARCA, dual-axis rotational coronary angiography; CCA, conventional coronary angiography.

It is noteworthy that image acquisition by DARCA is at 30 frames per second and that the patient stays away from the X-ray detector in order to accommodate the rotation. Even so, the decrease in the total number of runs in DARCA group compared with CCA group, may explain the overall reduction in the amount of radiation to the patient. These findings are consistent with all previous studies, with reductions ranging from 32% to 62%[6,7,9,11] and 50.4% in the current study. Although the current and previous studies have not evaluated operator radiation dose, the reduction of radiation exposure to the operator may be even more significant since the moments of greater radiation exposure are well concentrated in both rotations, when the operator can easily walk away from the X-ray tube. The issue of radiation exposure during imaging procedures has received increased attention. Given a potential lifetime of radiation exposure and its stochastic effects, even a small decrease may be clinically significant. Ionizing radiation can cause chromosomal changes and at high doses is associated with an increase in the probability of malignant tumors.[15,16] Therefore, one of the current standards for cardiac catheterization laboratories is for patient and operator radiation exposure to be reduced to as low as can reasonably be achieved.[17]

Although the present study enrolled patients with a high prevalence of CAD, the quality of image and information obtained with the DARCA method were appropriate, given that fewer patients require extra projections to define the coronary anatomy compared with CCA (54.4% vs. 75.0%). Furthermore, a noted advantage of the DARCA method is that once the rotation is held, the operator can determine the best angle for an ideal extra projection.

Previous studies have yielded conflicting results regarding the duration of DARCA versus CCA, some showing a reduction[6,7,11] and others showing a marked increase;[9] the latter clearly shows a learning curve with time procedure equivalence when considering only the last 50 patients of the protocol. Our study showed an increase in the average procedure time of 1 minute and 10 seconds in the DARCA group, most likely related to the time spent putting the heart at isocenter position in the AP and left-lateral views, an essential step of the rotation. This fact also explains the overall increase in fluoroscopy time. Finally, our study included a comprehensive subgroup analysis, showing that the benefits in contrast and radiation reductions were evident in all patient profiles and that the benefit of lower radiation exposure was higher in obese patients.

In one study by Grech et al. the authors randomly assigned to 1 of 4 groups depending on which machine and modality was used: monoplane conventional, monoplane DARCA, biplane conventional, and bi-plane DARCA. DARCA was significantly superior to all other modalities by reducing patient contrast and radiation doses and reducing procedure time. Nevertheless, bi-plane angiography alone, in case of DARCA unavailability, may be an acceptable option to reduce the amount the contrast dye in patients with impaired kidney function.[7]

Our study has some limitations that should be acknowledged. We did not directly measure the radiation exposure to the operator. There is also no direct comparison of the accuracy between methods; however, the fact that fewer patients in DARCA group required additional projections and that the average number of complementary projections was similar for both groups suggests that the quality of information obtained by DARCA is at least as good as CCA. In addition, the present analysis has limited external validity since it applies only to diagnostic coronary angiography and not for PCI, which is responsible for the higher radiation exposure during contemporary interventional approach.

In conclusion, in a population with a high prevalence of CAD, rotational coronary angiography provides good information, is safe, and results in a significant decrease in contrast volume and radiation dose compared with CCA. These benefits were evident in all subgroups analyzed and the benefit of lower radiation exposure was higher in obese patients.

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