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RESEARCH ARTICLE

Radiation Dose Reduction Comparing Dual Axis Rotational Coronary Angiography against Conventional Coronary Angiography in a Population with 100% Suspected Coronary Artery Disease: A Randomized Trial

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Abstract

Objective: We sought to compare the radiation dose, contrast volume, and procedure time between dual-axis rotational coronary angiography (DARCA) and conventional coronary angiography (CCA) techniques in a setting characterized by a prevalence of 100% suspected coronary artery disease.

Background: Previous studies have shown a reduction in radiation dose and contrast volume using DARCA, but these results have not been replicated in coronary artery disease (CAD) populations.

Methods: All-comers, prospective, randomized, open-label trial. Cine acquisition dose-area product (DAP), cumulative Air Kerma (AK), effective dose (E), fluoroscopic time, contrast volume, AK, cine acquisition DAP (CADAP), fluoroscopic DAP (F-DAP) and total DAP were compared between DARCA and CCA groups.

Results: We included 503 consecutive patients with suspected CAD, 252 assigned to DARCA and 251 to CCA. Stable coronary artery disease in 465 cases and non-ST elevation acute coronary syndrome in 38. Mean age: 61.88 ± 11.2 years, male gender 70.2%. DARCA arm patients showed lower total E dose (6.85 (4.55-10.83) vs. 7.91 (5.58-11.94) Sv; $p = 0.0023$), and cine E (3.00 (2.00-4.00) vs. 4.00 (3.00-5.00) Sv; $p < 0.0001$). Total DAP was also lower (40.3 (26.8-63.7) vs. 46.5 (32.8-70.2) $Gycm^2$; $p = 0.0023$, as a consequence of a lower CADAP (16.3 (10.5-22.9) vs. 23.4 (17.4-32.0) $Gycm^2$; $p < 0.0001$, with lower AK (367 (248-1497) vs. 497 (381-1827) mGy; $p < 0.0001$, with less contrast medium used (90 (60.0-106.0) vs. 100 (75.0-120.0) ml; $p = 0.014$.

Conclusion: In a population with 100% suspected coronary artery disease, DARCA reduces contrast material volume and radiation dose compared with CCA.

Abbreviations

CCA: Conventional Coronary Angiography; DARCA: Dual-Axis Rotational Coronary Angiography; CAD: Coronary Artery Disease; CAG: Coronary Angiography; VTG: Ventriculography; AK: Air Kerma; DAP: Dose-Area Product; CADAP: Cine Acquisition Dose-Area Product 15

Introduction

Exposure to ionizing radiation has nearly doubled since the 1980s [1,2] cardiac catheterization has become significant source of radiation exposure [2]. Patient radiation safety is a priority [3]. It is essential to minimize radiation dose when possible [4,5]. Angiographs manufacturers have made significant strides in reducing dose, however, operator dose management is still critical to the ALARA (As Low As Reasonably Achievable) principle [6,7]. Conventional coronary angiography remains the gold standard diagnostic exam in patients with coronary artery disease. However, there are limitations to this technique in the setting of complex coronary anatomy [8,9] Diagnostic inaccuracy of coronary angiography has been explained by the use of relatively few acquisitions in intent to minimize patient exposure, usually 4 to 6 views for the left coronary tree and 2 to 3 for the right coronary artery [10]. Dual-axis rotational coronary angiography (DARCA) has been introduced to overcome these limitations. DARCA consists of a type of rotational angiography with simultaneous cranial-to-caudal and left anterior oblique-to-right anterior oblique acquisition arcs, so each coronary can be completely evaluated

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using only 2 acquisitions. Previous studies have shown a reduction in radiation dose and contrast volume using DARCA [11-13], but these results have not been replicated in specific studies in a population with a high prevalence of coronary artery disease. Therefore, we sought to compare the radiation dose, contrast volume, and procedure time between the DARCA and CCA techniques in a setting characterized by a high prevalence of CAD.

Methods

The present study is some all-comers, prospective, randomized, open-label trial that includes patients older than 18 years referred to elective coronary angiography (CAG) or CAG + left ventriculography (VTG).

Between March 2016 and April 2017, a total of 503 consecutive patients with suspected CAD who underwent elective CAG or CAG + VTG were 1:1 randomized to DARCA or CCA. Patients with cardiogenic shock at arrival, valvular heart disease, cardiomyopathy or history of coronary artery bypass grafting were previously excluded.

Angiography protocol

An Allura Xper FD 10 digital X-ray system (Xper Swing TM Philips Healthcare, Eindhoven, The Netherlands) was used for DARCA or CCA. According to the manufacturer, the system is designed to reduce patient entrance dose significantly. Low-osmolar or iso-osmolar non-ionic contrast agents were injected manually through a 6 or 5 French catheter. CCA was performed in 4 to 6 acquisition runs for the LCA (RAO-caudal, RAO-cranial, LAO-cranial, anteroposterior (AP) cranial, AP caudal and LAO-caudal) and in 2 to 3 acquisition runs for the RCA (LAO, RAO, and LAO-cranial). DARCA was performed in a single run for each coronary artery. Additional projections were allowed at operator's discretion to better define the coronary anatomy.

DARCA acquisition

Following appropriate coronary catheterization, RA requires finding the Isocenter using fluoroscopy in the AP position by table panning and then in the left lateral position (LAO 90°) by elevating or lowering the table. 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. 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.

DARCA acquisition was obtained at 30 frames per second on 27 cm magnification, whereas CCA acquisition was obtained at 15 frames per second on 22 cm magnification. Five experienced operators participated in the study and were encouraged to not modify their usual coronary angiography routines.

Data collection and study endpoints

Radiation doses were automatically recorded as dose area product (DAP) in Gycm^2 and as cumulative Air Kerma (AK) in mGy, at procedure time. DAP is a surrogate measurement for the entire amount of energy delivered to the patient by the x-ray beam and is most often utilized in estimating stochastic risk [14]. Kerma is an acronym for "kinetic energy released in material"; AK represents the energy extracted from the x-ray beam per unit of mass of air in a small-irradiated air volume. Approaches to patient dosimetry are different for procedures that involve the use of fluoroscopy equipment. During these examinations, the tube amps and Kilovolts change continuously because of changes in attenuation through the patient. This means that it is difficult to monitor maximum entrance surface dose (ESD) directly. In these circumstances, DAP or AK area product are assessed and they are easy to measure and to correlate with risk. Additionally, they are independent of the distance from the X-ray tube [15,16]. We use here the dose-area product (DAP), equivalent to air kerma-area product (KAP) proposed by the International Commission on Radiological Units (ICRU 2005) [17]. The dose delivered to the patient is typically measured as "effective dose" (E) in Sievert units (Sv). The International Commission on Radiation Units and Measurements recommends that stochastic and deterministic risks associated with medical exposures be assessed from a detailed knowledge of organ doses, absorbed dose distribution, age and sex [17]. Effective dose is not considered suitable for this purpose by the ICRU. Since, many authors used effective dose as a surrogate quantity to assess patient exposures despite its limitations, in part because it is convenient to use, the latter has been used in this report for purposes of comparison with previous publications. The DAP obtained at procedure time was converted into E using a conversion factor of 0.17 mSv/Gycm^2, as validated by the National Radiological Protection Board (NRPB) [15].

The primary endpoint of this study was to compare the radiation dose measured by cine acquisition DAP and cumulative AK between DARCA and CCA during elective diagnostic CAG and CAG + VTG. Effective dose in Sv, fluoroscopic time (FT) in minutes, contrast volume in ml, AK, cine acquisition DAP (CADAP), fluoroscopic DAP (F-DAP) and total DAP were compared between groups. Baseline demographics and access site were also recorded.

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 (mean ± SD) or median and interquartile range 25-75% median (IQR). The sample distribution was evaluated by the Kolmogorov-Smirnov test. Variables were compared using the Student's t-test (normal distribution) or nonparametric Wilcoxon and Mann-Whitney tests (non-normal distribution). We estimated that 250 subjects in each group would be necessary to detect a 25% reduction in radiation dose with DARCA, with a power of 90%, level of significance of 5%, and 5% of loss of information. A p value of < 0.05 (2-sided) was considered statistically significant. All the procedures were performed in a single catheterization laboratory. The study was approved by the Ethics Committee at our hospital and signed informed consent was obtained from all patients.

Results

We included 503 consecutive patients, 252 assigned to DARCA and 251 to CCA, 265 underwent elective diagnostic CAG (46.4% DARCA and 53.6% CCA) and 238 underwent CAG + VTG (54.2% DARCA and 45.8% CCA). Indications for angiography were stable CAD in 465 cases and non-ST elevation acute coronary syndrome in 38. The mean was 61.88 ± 11.2 years and the majority (353/503; 70.2%) were male. There were no differences between groups neither in baseline characteristics nor in access site and no differences in coronary angiographic extension between groups (Table 1). At least 1 additional projection was required in all DARCA patients, the total number of projections for the group in order to achieve an effective diagnostic procedure was 2.43 ± 0.97.

Table 1: Baseline characteristics and Coronary disease extension.

	DARCA		CCA		p value
Age (years)	61.8 ± 11.2		61.9 ± 11.2		0.83
BSA (m^2)	1.85 ± 0.20		1.88 ± 0.18		0.67
BMI (kg/m^2)	28.7 ± 5.03		29.0 ± 4.65		0.40
	n	%	n	%	
Male gender	173	49.0	180	51.0	0.51
Femoral access	137	54.4	142	56.6	
Right radial access	99	39.3	92	36.6	
Left radial access	16	6.3	17	6.8	0.82
< 70% stenosis	23	9.13	20	7.97	
1 vessel disease	105	41.67	110	43.82	
2 vessel diseases	70	27.78	68	27.09	
3 vessel disease	54	21.43	53	21.12	0.86

DARCA: Dual-Axis Rotational Coronary Angiography; CCA: Conventional Coronary Angiography; BSA: Body Surface Area; BMI: Body Mass Index.

As expected DAP was higher in patients who underwent to CAG + VTG (46.7 $Gycm^2$; IQR: 32.4-69.5 vs. CAG alone 40.2 $Gycm^2$; IQR: 28.7-63.4; p = 0.034), due to a higher CADAP exposure (21.8 $Gycm^2$; IQR: 15.6-30.6 vs. 17.7 $Gycm^2$; IQR: 13.1-25.8; p < 0.0001). No difference was found in AK regarding type of procedure (CAG + VTG: 463 mGy; IQR: 312-642 vs. CAG: 425 mGy; IQR: 292-629; p = 0.18. When we compared DARCA with CCA, although total fluoroscopy time was similar, the volume of contrast used was higher in CCA group. We observed that patients randomized to DARCA arm had lower total effective delivered dose, and cine effective dose delivered. Total DAP was also lower, mainly at the expense of a significantly lower CADAP. In the same way, the AK was significantly lower, together with a significant reduction in the amount of contrast medium used in the DARCA group (Table 2).

Discussion

The present trial has demonstrated that the use of DARCA does reduce patient dose exposure and contrast volume during cine acquisition in a CAD suspected population., despite the required number of additional projections in order to achieve an effective procedure. Obviating use of x-ray imaging for guidance during cardiac catheterization would be the ultimate solution and could be achieved by with magnetic resonance imaging. Such systems have been used for structural interventions at a few centers in the United States and England

Table 2: Radiation exposure.

	DARCA	CCA	p value
Total E (Sv)	6.85 (4.55-10.83)	7.91 (5.58-11.94)	0.0023
Cine E (Sv)	3.00 (2.00-4.00)	4.00 (3.00-5.00)	0.0001
CADAP ($Gycm^2$)	16.3 (10.5-22.9)	23.4 (17.4-32.0)	0.0001
F-DAP ($Gycm^2$)	24.1 (13.3-38.6)	21.6 (12.1-38.3)	0.43
Total DAP ($Gycm^2$)	40.3 (26.8-63.7)	46.5 (32.8-70.2)	0.0023
AK (mGy)	367 (248-1497)	497 (381-1827)	0.0001
Fluoroscopic time (minutes)	4.9 (3.0-8.0)	5.0 (3.0-9.0)	0.92
Contrast material volume (ml)	90 (60.0-106.0)	100 (75.0-120.0)	0.014

DARCA: Dual-Axis Rotational Coronary Angiography; CCA: Conventional Coronary Angiography; E: Effective Dose; CADAP: Cine Acquisition Dose-Area Product; F-DAP: Fluoroscopic Dose-Area Product; AK: Air Kerma; All values are median (IQR).

but do not have sufficient temporal resolution for coronary artery imaging and require continued hardware development (such as active magnetic resonance imaging catheters) before implementation in routine clinical practice.

In the meanwhile, the "as low as reasonably achievable" (ALARA) principle, based on the linear-no threshold model of radiation cancer risk, should guide all medical uses of radiation. There are multiple ways to limit radiation exposure in the cardiac catheterization laboratory, such as reducing the fluoroscopy frame rate and cine angiography projections and optimizing X-ray emitter positioning [18].

Previous studies have showed conflicting results regarding the procedure time of DARCA versus CCA, some showing a reduction [12,19,20], and others showing a marked increase in it [13]; the latter clearly shows a learning curve. We did not found differences in fluoroscopic time between groups, despite the time spent in finding the Isocenter, an essential step when performing the DARCA.

A significant 11% 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% [12,13,18-20] this could be explained on the image acquisition requirements of the current study population (100% CAD).

Study limitations

Our study has some limitations that should be acknowledged. We did not directly measure the radiation exposure to the operator. There is no direct comparison of the diagnostic accuracy between methods. 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.

Conclusion

In a population with 100% suspected coronary artery disease, rotational coronary angiography provides accurate information on coronary angiographic disease, is safe, and results in a significant decrease in contrast material volume and radiation dose compared with CCA. Applying dual-axis rotational coronary angiography in this particular population, were multiple projections are usually required, will contribute to reduce medical radiation exposure and to accomplish the ALARA Principle.

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