Efficacy and safety of dual-axis rotational coronary angiography versus conventional angiography

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ABSTRACT

Background
Conventional coronary angiography (CA) is the gold standard for the diagnosis of coronary artery disease. However, this technique requires several orthogonal projections to determine the severity of the disease. Dual-axis rotational coronary angiography (DARCA) is a new technique which acquires the image of each coronary artery using a single contrast injection, potentially reducing both radiation and contrast exposure.

Objective
The aim of this study was to determine the amount of contrast used, radiation exposure and diagnostic accuracy of DARCA compared to conventional CA.

Methods
We conducted a prospective, self-controlled study of consecutive patients undergoing elective coronary angiography to compare DARCA versus the conventional technique. All the angiographies were reviewed by two independent interventional cardiologists (observer 1 and observer 2) who evaluated agreement between both types of images. The observers evaluated firstly DARCA and three weeks later conventional CA images to prevent bias in their interpretation.

Results
The contrast volume used in the diagnostic procedure was significantly lower with DARCA (33.29 ± 11.2 ml vs. 17 ± 5.4 ml; $p < 0.01$). Radiation exposure in the patient (235.6 ± 76.8 mGy vs. 82.7 ± 46.6 mGy; $p < 0.01$) and operator was also significantly lower (5.7 ± 3.26 µSv vs. 2.48 ± 1.47 µSv; $p < 0.04$). A slight difference and a strong correlation were seen in the number of lesions, vessel diameter and percentage of stenosis between both observers and both methods. Categorical assessment of percentage of stenosis also showed adequate agreement.

Conclusion
DARCA reduces the use of contrast agents and radiation exposure compared to the conventional technique without modifying the diagnostic accuracy of the method.

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Abbreviations >	**CA**	Conventional angiography	**mGy**	Miligray
	DARCA	Dual-axis rotational coronary angiography	**µSv**	Microsievert
	RCA	Right coronary artery		

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BACKGROUND

Despite the increasing progress in cardiac imaging techniques, conventional angiography (CA) is still the standard diagnostic tool for the evaluation of coronary artery lesions and therapeutic strategy. (1)

However, CA has some limitations, such as the risk of contrast-induced nephropathy and radiation exposure of patients and hemodynamics laboratory staff. (2, 3)

The introduction of dual-axis rotational coronary angiography (DARCA), in which the C-arm rotates in two axes during scanning has allowed visualization of the coronary tree by using a single contrast injection. (4-6)

Thanks to this novel technique of image acquisition that entails automatic gantry movement following a left to right and cranial to caudal trajectory, the entire coronary tree is visualized. This movement has been adjusted to obtain all the projections of the CA, including the optimal projections of each segment, without vessel overlap and foreshortening. (6)

Several studies have demonstrated the feasibility and safety of DARCA for coronary artery evaluation. (7) However, the diagnostic accuracy of the method should be similar to that of CA to be considered as a standard method.

So far, current evidence on the performance and diagnostic safety of DARCA is limited.

The goal of this study is to determine the safety and diagnostic accuracy of DARCA compared to CA.

METHODS

Sample selection
This prospective study was designed to compare the feasibility, diagnostic accuracy and safety of DARCA versus conventional CA.

Population
Consecutive patients undergoing diagnostic coronary angiography were included. The study was performed in the Department of Interventional Cardiology and Endovascular Therapeutics at the Instituto Cardiovascular de Buenos Aires using a Philips Allura FD 20 system. All patients gave their informed consent prior to inclusion in the study. Patients with acute coronary syndromes, history of revascularization surgery and diagnosis of previous kidney failure (creatinine levels > 1.3 mg/dl) were excluded from the study.

Angiography
The choice of vascular access was left to the operator's discretion. Hypoosmolar contrast agent was injected manually following the standard protocol procedure. In all cases 6 French diagnostic catheters were used.

Conventional angiography was systematically performed in four projections for the left coronary artery (right anterior oblique-caudal, antero-posterior cranial, left anterior oblique-cranial and left anterior oblique-caudal) and in two projections for the right coronary artery (RCA) (left anterior oblique and antero-posterior cranial). The field of view was of 22 mm with image acquisition of 15 frames per second.

When conventional angiography ended, patients underwent DARCA. The isocenter was adjusted before image acquisition.

Total duration did not include the time taken to place the catheter in the artery under fluoroscopy and to adjust the isocenter.

DARCA acquisition is automated; therefore, the rotating C-arm follows a pre-established trajectory (Figure 1). Moreover, the duration of the C-arm movement and image acquisition are fixed: 5.3 seconds for the left coronary artery and 4 seconds for the right coronary artery.

Patients with total or severe occlusion of the RCA ostium or poorly developed and small caliber RCA were excluded from DARCA.

Analyzed variables and objectives
Procedure-related data (milliliters of contrast agent, patient and staff radiation exposure), angiographic data, patient risk factors, demographic information and procedure-related complications were prospectively collected.

The total radiation delivered during acquisition with both techniques was measured using air-kerma rate (mGray). Operator radiation exposure was also measured. Both radiations were measured for each diagnostic method with digital dosimeters placed outside the lead apron in the workplace following basic protection procedures.

The studies were evaluated by two independent, blinded, interventional cardiologists (observer 1 and observer 2) to determine the diagnostic accuracy of DARCA.

The observers reported the number of lesions (greater than 50% for the total number of patients) and their characteristics (percentage of stenosis and vessel length and size) observed with both techniques. According to the protocol, DARCA was evaluated firstly and CA was examined three weeks later. In order to minimize the margin of error in estimating lesion length, 30/82 (36.5%) lesions were selected with the same location in the coronary tree assessed by both methods and by both observers. Lesions were stratified in three groups: short (< 10 mm), intermediate (10-20 mm) and long (< 20 mm).

Statistical Analysis
Continuous variables were expressed as mean ± standard deviation. The t test or the Kruskal-Wallis test was used
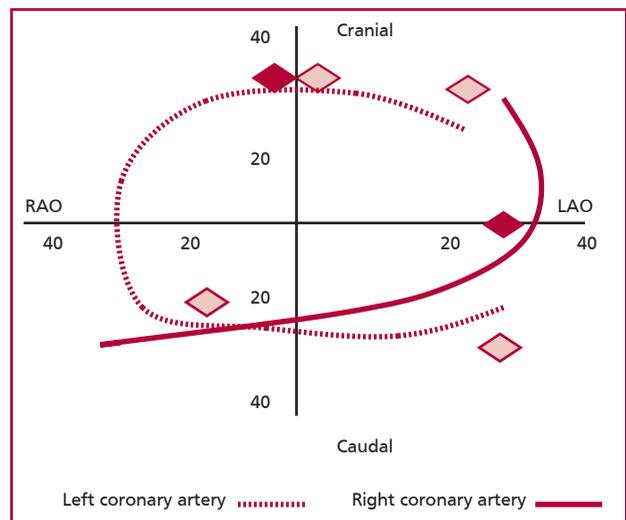
Fig. 1. Image acquisition with DARCA and CA. RAO: Right anterior oblique view. LAO: Left anterior oblique view. Lines: Detector trajectory during acquisition with DARCA. Diamonds: Automated acquisitions.

to compare two groups with parametric or non-parametric distribution, respectively. Categorical variables were expressed as percentages and were compared using the chi square test or Fischer's test as applicable. A p value < 0.05 was considered statistically significant.

Quantitative agreement between both techniques was established by means of the correlation coefficient and the results were graphically analyzed with the classic Bland-Altman method. The level of categorical variable inter-observer and inter-method agreement was analyzed using Cohen's kappa coefficient. Statistical analysis was performed using SPSS 18.0.0 statistical package for Windows, Chicago, Ill, USA.

RESULTS

Patient characteristics
Forty four patients were included: 80% were men and the majority had multiple risk factors (80% hypertension, 22.5% diabetes mellitus and 23.5% had smoking habits). One third of the patients had previous history of coronary artery disease, while 95.4% presented lesions greater than 50%, totalizing 82 lesions.

DARCA of the left coronary artery was performed in all patients; however, this method could not be used in the right coronary artery in eight patients due to the presence of ostial lesions with significant damping (two patients), proximal occlusion (two patients) and nondominant right coronary artery (four patients).

No complications were reported with both methods in the analyzed patients.

Contrast volume
The contrast volume used in DARCA was 45.4% lower than that used in CA (CA 33.29 ± 11.2 ml vs. DARCA 17 ± 5.4 ml; p < 0.01) (Figure 2).

The use of contrast agent decreased significantly in the left coronary artery (CA 28.1 ± 10 ml vs. DARCA 12 ± 2.9 ml; p < 0.03), while there was only a slight reduction in the RCA (CA 5.1 ± 4 ml vs. DARCA 4 ± 2.9 ml; p < 0.06).

Radiation
Patient radiation exposure was significantly lower with DARCA (CA 235.6 ± 76.8 mGy vs. DARCA 82.7 ± 46.6 mGy; p < 0.01) (65.4% total exposure reduction). This reduction was still significant when both arteries

were evaluated separately (in the left coronary artery: CA 186 ± 68.3 mGy vs. DARCA 52.9 ± 30.2 mGy; p < 0.01; in the RCA: CA 49.6 ± 44.5 mGy vs. DARCA 29.8 ± 6 mGy; p < 0.03).

Operator radiation exposure also decreased with DARCA compared to CA (CA 5.7 ± 3.26 μSv vs. DARCA 2.48 ± 1.47 μSv; p < 0.04 (see Figure 2).

Lesion evaluation
Of the 82 relevant lesions, 21 were bifurcation lesions, 6 were total occlusions, 5 were left main coronary artery lesions and 3 were intrastent restenosis. All the lesions were detected by both observers using both methods.

Intra-observer variability: observer1 and observer 2
Independently of the observer, a slight, non-significant difference and a strong correlation could be seen in the number of lesions, vessel diameter and percentage of stenosis with both methods (Table 1). In the case of percentage of stenosis evaluation with both methods, ≤ 10% difference was observed in 90 % and 83.4% of the lesions assessed by observers 1 and 2, respectively (Figure 3). The Bland-Altman plot (Figure 4) shows that most of the observations lie within the 95% CI and does not suggest presence of systematic errors. In addition, there was an optimal agreement between observer 1 and observer 2 in the evaluation of lesion length (Table2).

*Inter-observer variability: observer 1 versus observer 2*
No significant differences were noticed in the number of lesions, vessel size and percentage of stenosis evaluated by both observers with DARCA (Table 1). Less than 10% difference was observed for percentage of stenosis in 66.7% of lesions evaluated by DARCA and in 86.8% lesions assessed by CA (see Figure 3). The Bland-Altman plot (Figure 5) shows that most of the observations lie within the 95% CI and does not suggest presence of systematic errors.

DISCUSSION
The following results should be highlighted:
1. The exposure to contrast agents and radiation is lower in DARCA than in CA.

Fig. 2. Contrast volume and radiation exposure according to the method.
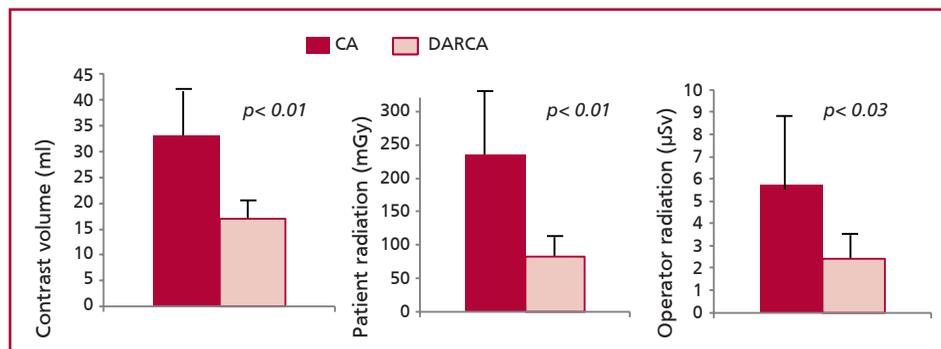
Table 1. Evaluation of lesion characteristics according to the observer and angiographic method

| | | Observer 1 | | | Observer 2 | |
	CA	DARCA	Delta*/Correlation**	CA	DARCA	Delta*/Correlation**
Number of lesions	2 ± 0.9	1.9 ± 1	0 (0 a 0.25)/r = 0.70	2.2 ± 1.1	1.8 ± 1.1	0 (0 to 1)/r = 0.8
Vessel diameter (mm)	2.92 ± 0.45	2.95 ± 0.66	0 (-0.3 to 0.5)/r = 0.77	2.8	2.8 ± 1.3	0 (-5 to 5)/r = 0.76
Stenosis (%)	73 ± 17	72 ± 17	0 (-5 to 0)/r = 0.77	73 ± 16	75 ± 18	0 (0 to 5)/r = 0.87

*Delta (CA DARCA) is expressed as median (25-75% interquartile range). **(CA vs. DARCA).
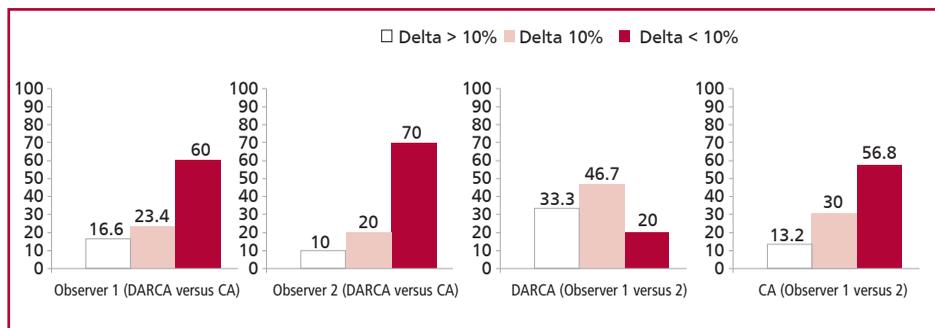
Fig. 3. Categorical comparison of percentage of stenosis between observers and between methods. Delta (observer 1 minus observer 2 or DARCA minus CA) was divided into three groups: < 10%, 10% and >10%.

2. The diagnostic accuracy of DARCA is similar to that of CA.

The use of diagnostic imaging tests such as computed tomography, arteriography and coronary angiography, among others, is a common medical practice associated with a not negligible nefrotoxicity risk. Contrast-induced nephropathy represents the third most common cause of intrahospital acute renal failure and its incidence in the literature varies significantly due to different definitions of contrast-induced nephropathy and the type and volume of administered contrast agent. (8, 9) Several studies confirm the impact of contrast-induced nephropathy in short- and long-term cardiovascular survival. In this sense, the reduction in contrast volume used with DARCA might have a favorable impact in patient outcome. (10) In addition, the use of lower contrast volume might be promising for patients with hemodynamic instability and volume overload. (10, 11) More studies are needed to clarify these issues.

Percutaneous interventions and reinterventions have increased due to greater life expectancy and progress in interventional cardiology. Thus, it is necessary to reduce the cumulative exposure to x-rays in patients with cardiovascular diseases. DARCA is an efficient tool to reduce administered radiation dosage as images are acquired at a speed of 30 frames per second. (12, 13) The use of special software associated with DARCA helps to choose the correct working position, with lower vessel overlap and foreshortening in all vessel segments, to program the therapeutic intervention after the three-dimensional reconstruction of the coronary tree.

Similarly, rotational X-ray tube motion allows a better space location avoiding repetitive acquisitions during the intervention. In addition, reduction of operator radiation exposure is an advantage especially in high-volume centers with complex, prolonged procedures.

Despite our study was conducted on a small number of patients, we have included a broad spectrum of coronary artery diseases. However, no hemodynamic complications or arrhythmias were reported in agreement with previous publications. (6) These findings supplement the safety concept of the technique described in this study.

The diagnosis of coronary artery lesions with DARCA was comparable to that of CA in the number and characteristics of the evaluated lesions. These findings are similar to those reported in previous studies; however, our experience is the first one evaluating both methods by two independent and blinded interventional cardiologists, conferring reliability to the two methods. (6) Moreover, the diagnostic accuracy of the method is high according to this study as the interpretation of lesions > 50% have been similarly characterized by independent specialists.

CONCLUSIONS
DARCA is a safe diagnostic method to perform coronary angiographies. This technique is feasible to use in routine medical practice reducing radiation dosage and contrast volume. Moreover, the study has revealed image quality equivalent to that of conventional methods associated with an adequate diagnostic interpretation.

Fig. 4. Bland-Altman plots comparing both methods.
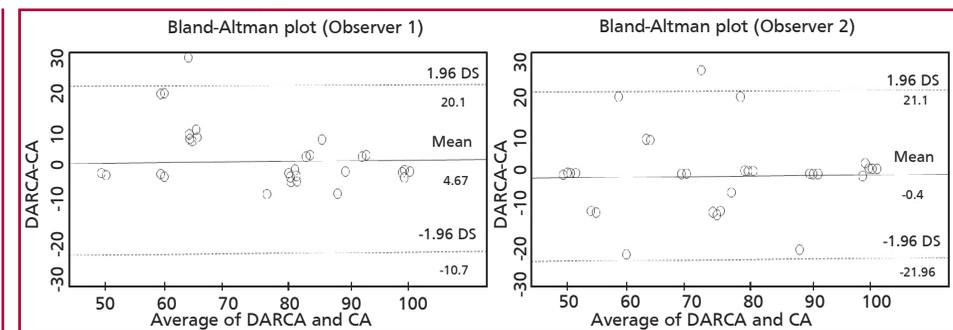
Fig. 5. Bland-Altman plots comparing both observers.
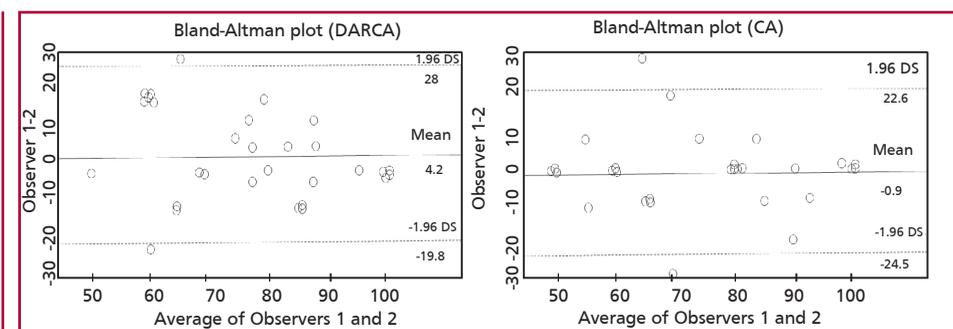
Table 4. Results of multivariate analysis

Observer 1		DARCA (n = 30)			Total
		≤ 10 mm	11-20 mm	> 20 mm	
CA (n = 30)	≤ 22	7	2	0	9
	11-20 mm	0	13	0	13
	> 20 mm	0	0	8	8
	Total	7	15	8	30

Level of agreement (kappa index): 0.92

Observer 2		DARCA (n = 30)			Total
		≤ 10 mm	11-20 mm	> 20 mm	
CA (n = 30)	≤ 22	7	3	0	10
	11-20 mm	2	11	3	16
	> 20 mm	0	0	4	4
	Total	9	14	7	30

Level of agreement (kappa index): 0.61

RESUMEN

Angiografía coronaria con técnica rotacional doble: eficacia y seguridad frente a la coronariografía convencional

Introducción
La angiografía convencional (AC) es la técnica de referencia para el diagnóstico de la enfermedad coronaria. Sin embargo, requiere múltiples proyecciones ortogonales para determinar el grado de enfermedad. La técnica de angiografía rotacional dual (ARD) permite una única adquisición e inyección de contraste para cada coronaria, con potencial reducción del volumen de contraste y de la dosis de radiación.

Objetivo
Comparar ambas técnicas (AC vs. ARD) a través de la evaluación de cantidad de contraste, exposición a la radiación y eficiencia diagnóstica.

Material y métodos
El presente es un estudio prospectivo, consecutivo, autocontrolado de coronariografías electivas para comparar AC y ARD. Todas las angiografías fueron revisadas por dos hemodinamistas independientes (observador 1 y observador 2) para evaluar la concordancia entre ambos tipos de imágenes. Para prevenir un sesgo en la lectura de las imágenes, los observadores evaluaron primero las ARD y tres semanas más tarde hicieron lo propio con las AC.

Resultados
Con la ARD se observó una reducción en la utilización de contraste (33,29 ± 11,2 ml vs. 17 ± 5,4 ml; p < 0,01) y en la exposición a radiación del paciente (235,6 ± 76,8 mGy vs. 82,7 ± 46,6 mGy; p < 0,01) y del operador (5,7 ± 3,26 μSv vs. 2,48 ± 1,47 μSv; p < 0,04). Se observó una leve diferencia y una fuerte correlación en el número de lesiones, diámetro del vaso y porcentaje de estenosis entre ambos observadores y entre ambos métodos. La evaluación categórica del porcentaje de estenosis también demostró una concordancia adecuada.

Conclusión
La ARD reduce el uso de contraste y la exposición a radiación en comparación con la técnica convencional, sin alterar la eficiencia diagnóstica del estudio.

Palabras clave > Angiografía rotacional - Enfermedad coronaria - Radiación

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