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REVIEW ARTICLE

Safety and efficacy of dual-axis rotational vs standard coronary angiography: meta-analysis

Seguridad y eficacia de la angiografía coronaria rotacional de doble eje vs. angiografía coronaria estándar: metaanálisis

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Abstract

The objective is to compare the safety and efficacy of dual-axis rotational coronary angiography (DARCA) with standard coronary angiography (SA). We performed a systematic review and meta-analysis comparing the efficacy of coronary lesions visualization and safety endpoints for patients with suspected coronary artery disease undergoing DARCA and SA. We searched PubMed, Google Scholar, and Cochrane databases for head-to-head trials. Mean differences (MD) with 95% confidence intervals (CI) were pooled with a random-effects model with a Paule-Mendel estimator using RStudio software. Three studies corresponding to 128 patients met the inclusion criteria. 128 (100%) patients underwent both DARCA and SA. Compared with SA, DARCA had no significant diagnostic accuracy difference for coronary lesion visualization (MD = −0.19 lesions per patient; 95% CI = [−0.52; 0.15]; p = 0.28) but was associated with a substantially lower contrast dose used (MD = −16.77 cm^3; 95% CI = [−26.00; −7.55]; p < 0.01) and radiation exposure (MD = −11.89 Gycm^2; 95% CI = [−17.09; −6.65]; p < 0.01). In the meta-analysis, DARCA had no significant difference in coronary lesion visualization and lower contrast and radiation used compared with SA.

Keywords: *Dual-axis rotational coronary angiography. Standard angiography. Safety. Efficacy. Head-to-head comparison.*

Resumen

Nuestro objetivo fue el de comparar la seguridad y eficacia de la angiografía coronaria rotacional de doble eje (DARCA) con la angiografía coronaria estándar (AS). Realizamos una revisión sistemática y un metanálisis comparando la eficacia de la visualización de lesiones coronarias y los criterios de valoración de seguridad para pacientes con sospecha de enfermedad coronaria (CAD) sometidos a DARCA y AS. Buscamos ensayos comparativos en PubMed, Google Scholar y bases de datos Cochrane. Las diferencias de medias (DM) con intervalos de confianza (IC) del 95% se agruparon con un modelo de efectos aleatorios con un estimador de Paule-Mendel utilizando el software RStudio. Tres estudios correspondientes a 128 pacientes cumplieron los criterios de inclusión. 128 (100%) pacientes se sometieron tanto a DARCA como a AS. En comparación con la angiografía asistida por sonda, la DARCA no mostró una diferencia

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significativa en la precisión diagnóstica para la visualización de lesiones coronarias (MD -0,19 lesiones por paciente; IC del 95% [−0.52; 0.15]; p = 0.28), pero se asoció con una dosis de contraste utilizada sustancialmente menor (MD = −16.77 cm^3; IC del 95% = [−26.00; −7.55]; p < 0.01) y una exposición a la radiación (MD = −11.89 Gycm^2; IC del 95% = [−17.09; −6.65]; p < 0.01). En el metanálisis, la DARCA no mostró una diferencia significativa en la visualización de lesiones coronarias y se utilizó un contraste y una radiación menores en comparación con la angiografía asistida por sonda.

Palabras clave: *Angiografía coronaria rotacional de doble eje. Angiografía estándar. Seguridad. Eficacia. Comparación directa.*

Introduction

Coronary artery disease (CAD) diagnosis is usually defined with standard coronary angiography (SA), an interventional imaging technique that displays the coronaries through four fixed points of view in most centers[1]. Past complications concerning the dose of contrast used and the radiation exposure in this diagnostic method arouse questions about the safety of SA and the search for new diagnostic methods[2-4].

At present, SA remains the preferred method for coronary imaging acquisition, notwithstanding, some concerns are mentioned in the literature: (1) risk for contrast-induced nephropathy for higher volumes of contrast; (2) long radiation exposure; (3) vessel overlap, foreshortening, and unappreciated tortuosity, and (4) the angiography acquisitions are operator-dependent, based on heuristic experience, and are limited by time, safety, and cost[2,3,5-7].

Dual-axis rotational coronary angiography (DARCA) is a novel automated technique to visualize the coronaries with two gantry rotations according to the anatomy of the right and left coronary arteries, summarizing those movements in a dynamic image for each coronary. The two gantry pathways of DARCA involve a simultaneous cranial-to-caudal and a left anterior oblique to right anterior oblique acquisition arcs, in contrast to traditional rotational angiography, requiring three gantry rotations, two for the left coronary artery and one for the right coronary artery[5].

A previous meta-analysis demonstrated a significant reduction in the contrast dose and the radiation exposure associated with DARCA[8]. However, there is no data assessing the diagnostic efficacy and accuracy of DARCA, therefore, a direct lesion comparison of patients undergoing DARCA and SA can be a meaningful way to strengthen the evidence of the efficacy of coronary visualization with DARCA.

Methods

Eligibility criteria

Inclusion in this meta-analysis was restricted to studies that met all the following eligibility criteria: (1) head-to-head comparison trials; (2) enrolling adult patients who underwent DARCA and SA; and (3) patients with suspected CAD. In addition, studies were included only if they reported any of the clinical outcomes of interest. We excluded studies with (1) different patients for intervention and control group; (2) post-cardiac surgery or pediatric patients; (3) non-comparative data; and (4) studies assessing vessels other than the coronaries.

Search strategy and data extraction

We systematically searched PubMed, Google Scholar, and Cochrane Central Register of Controlled Trials from inception to March 2024 with the following search terms: “dual-axis,” “DARCA,” “Xperswing,” “rotational angiography,” “accuracy,” “diagnostic,” “accuracy,” “prevalence,” and “efficacy.” The references from all included studies, previous systematic reviews, and meta-analyses were also searched manually for any additional studies. Two authors (S. R. and F. de M.) independently extracted the data following predefined search criteria and quality assessment. The prospective meta-analysis protocol was registered on the International Prospective Register of Systematic Reviews on April 1, 2024, under protocol 527370.

Endpoints

Safety endpoints included contrast dose and radiation exposure. The efficacy endpoint of interest was the mean number of lesions visualized on each method by reviewers separately, as well as combined data from reviewers in the same study. All included studies assessed coronary lesions by at least a pair of reviewers. In addition, the studies reported variability in inter-method agreement using the κ coefficient, Bland–Altman plot, and Likert score, which are summarized in supplementary table 1.

Quality assessment

All studies were appraised with two assessment tools: (1) Risk of Bias in Non-randomized studies – of interventions (ROBINS-I) in which seven domains: Confounding, selection of patients, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes and selection of reported results were analyzed for biases and scored as the low, moderate, severe or critical risk of bias; and (2) Modified Downs and Black checklist in which five domains: reporting, external validity, internal validity – bias, internal validity – confounding and power were analyzed for biases and scored as excellent, good, fair and poor quality.

Statistical analysis

This systematic review and meta-analysis was performed according to the Cochrane Collaboration and the Preferred Items for Systematic Reviews and Meta-Analysis statement guidelines. Mean differences (MD) with 95% confidence intervals (CI) were used to assess diagnostic effectiveness when comparing lesions visualization and safety outcomes on categorical endpoints. p-values inferior to 0.10 and $I^2 > 25\%$ were considered significant for heterogeneity. Cochran Q test and I^2 statistics were used to assess heterogeneity.

A Paul-Mandel random-effect model was used for contrast dose and radiation exposure measurements due to the small sample size, high heterogeneity, and the total number of studies. A fixed-effect model was used for the mean number of lesions visualized considering the low heterogeneity, the small number of studies included, and the significant similarities across studies to report efficacy data: (1) same patients in population and control group; (2) same criteria to define CAD; (3) more than one reviewer, and (4) inter-method agreement variability analysis. $p < 0.05$ were considered statistically significant.

Results

Study selection

As detailed in supplementary figure 1, the initial search yielded 1,035 results. After the removal of duplicate records and ineligible studies, 18 studies were fully reviewed based on inclusion criteria. Of these, three studies with 128 patients were included[6,9,10]. Study characteristics are reported in table 1. In two studies, all reviewers evaluated lesions in a blinded manner[6,10]. Content analysis of the control group was conducted 3 weeks following the intervention group in one study[10], and 4 weeks later at the earliest for the other study[6]. The latter included a third, blinded, independent reviewer for a quantitative coronary angiography report. All studies considered CAD as diameter stenosis ≥ 50%.

Pooled analysis of all studies

There was no significant difference in visualizing the mean number of coronary lesions visualized across the studies (MD = −0.19 lesions per patient; 95% CI = [−0.52; 0.15]; $p = 0.28$; $I^2 = 0\%$; Fig. 1A) and the mean lesions visualized individually (MD = −0.12 lesions per patient; 95% CI = [−0.36; 0.12]; $p = 0.32$; $I^2 = 0\%$; Fig. 1B). However, there was a significant association of DARCA with a reduction on contrast dose (MD = −16.77 cm^3; 95% CI = [−24.96; −7.58]; $p < 0.01$; $I^2 = 95\%$; Fig. 2A) and radiation exposure (MD = −11.89 $Gycm^2$; 95% CI = [−17.31; −6.48]; $p < 0.01$; $I^2 = 93\%$; Fig. 2B).

Quality assessment

All three studies were included in both quality assessment tools and are summarized in supplementary table 1. In one head-to-head trial, reviewers were not blinded by the study interventions, compromising the domain of measurement of outcomes[9]. One study did not use automatic contrast injections in any angiographic procedures[10]. In addition, only one study performed a power analysis to determine the sample size. Nevertheless, due to the head-to-head nature of all included trials, the overall risk of bias remains low in both ROBINS-I and Modified Downs and Black checklist quality assessment tools.

Discussion

In this systematic review and meta-analysis of three head-to-head trials and 128 patients with suspected CAD, we compared the efficacy and safety of DARCA and SA. Our main findings were: (1) no significant difference in diagnostic precision between groups and (2) a significant reduction in the contrast dose used and radiation exposure associated with DARCA.

Nephropathy induced by contrast (NIC) medium remains one of the most clinically significant

Table 1. Characteristics of studies included in the Meta-analysis

Characteristics	Klein 2011	Jin 2019	Nau 2012
Population	> 18 years undergoing diagnostic coronary angiography	> 18 years undergoing diagnostic coronary angiography	Consecutive patients undergoing diagnostic coronary angiography
Location	Denver – USA	Beijing – China	Buenos Aires – Argentina
Intervention	DARCA	DARCA	DARCA
Control group	SA	SA	SA
Study design	H-h comparison	H-h paired design trial	Prospective H-h
Image acquisition protocol	Patients first underwent SA followed by DARCA	Patients first underwent DARCA followed by SA	Patients first underwent DARCA followed by SA
No. of patients	21	63	44
Male, n (%)	29 (96.67)	30 (47.6)	35 (80)
Diabetes, (%)	4 (13.33%)	9 (14.3)	9 (22.5%)
Hypertension, (%)	23 (76.67%)	36 (57.1)	35 (80%)
Hyperlipidemia, (%)	25 (83.33%)	23 (36.5)	NA
Smoking history, (%)	19 (63.33%)	27 (42.9)	10 (23.5%)
Reviewers	2	2	2
Overall CAD, (%)	21 (70%)	Reviewer 1: 40 (63,5%) Reviewer 2: 34 (54%)	41 (95.4%)
CAD diagnostic criteria	Vessel diameter stenosis ≥ 50%	Vessel diameter stenosis ≥ 50%	Vessel diameter stenosis ≥ 50%
Method assessed	DARCA and SA evaluated at the same time	SA evaluated at the earliest 1 month after DARCA	SA evaluated 3 weeks after DARCA
SA technique	Left SA: four projections Right SA: two projections	Left SA: five projections Right SA: two projections	Four projections
Acquisition time DARCA (seconds)	LCA: 6.7 RCA: 3.96	LCA: 6.3 RCA: 4.5	LCA: 5.3 RCA: 4
SA image acquisition	15 fr/s	15 fr/s	15 fr/s
DARCA image acquisition	30 fr/s	15 fr/s	NA
Equipment	Philips FD20 digital X-ray	Allura Xper FD 10 digital	Philips Allura FD20
Catheter diameter (Fr.)	6	5	6
Catheter location	Femoral approach	Right radial	Operator's discretion
Contrast used	Iodixanol	Iopromide	Hypoosmolar agent
Injection	Assist Voyager system	Automatic pump	Manually

DARCA: dual-axis coronary angiography; SA: standard angiography; H-h: head-to-head; LCA: left coronary artery; RCA: right coronary artery; fr/s: frames per second; Fr: French; NA: not available.

complications caused by iodinated contrast medium[11], a commonly used contrast medium when performing an angiography. The minimization of contrast material volume can be a key management strategy to decrease the incidence of NIC and hospital-acquired acute renal failure as a co nsequence of a coronary angiography procedure[12]. Several previous trials have demonstrated a certain degree of contrast volume reduction in the use of DARCA when compared to SA[13-16].

Considering the growing number of cardiac imaging with ionizing radiation in the last decade[17], a

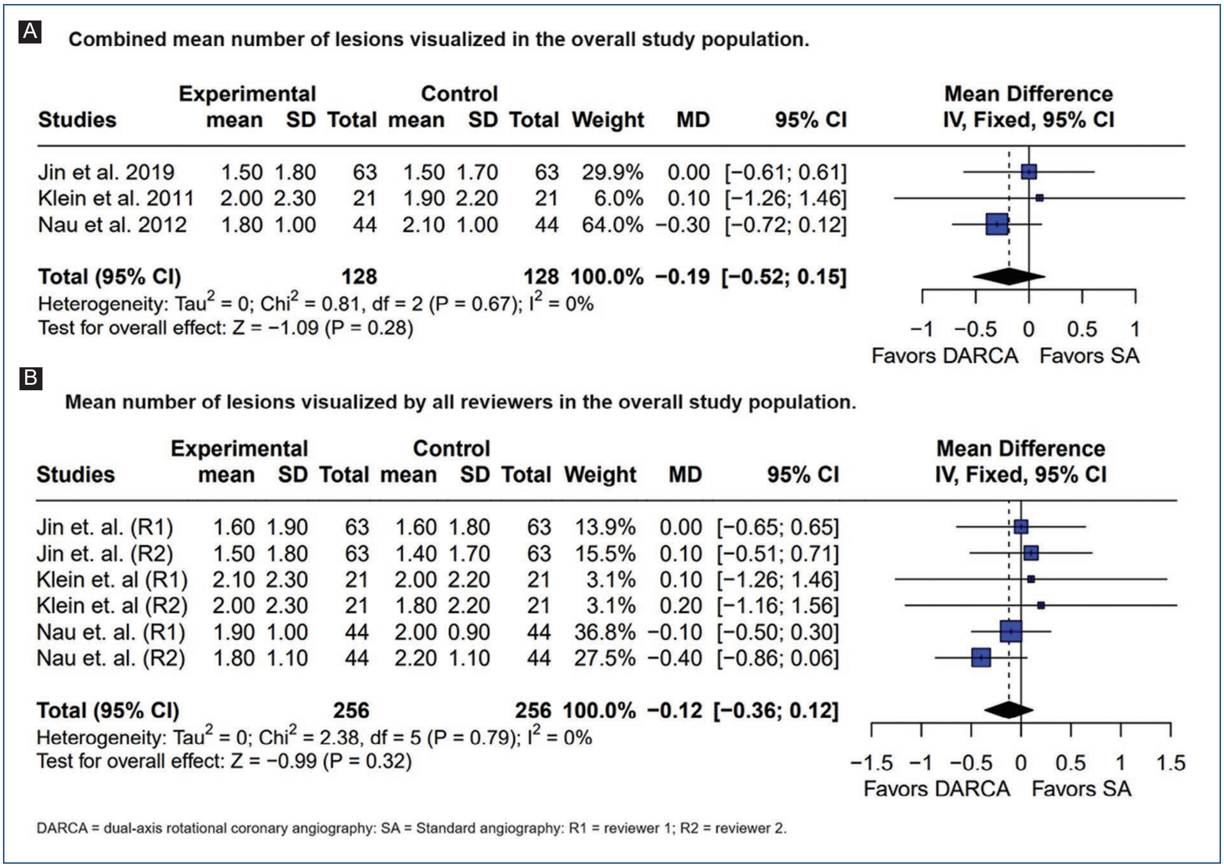

Figure 1. Forest plots comparing the mean number of coronary lesions visualized between dual-axis rotational coronary angiography (DARCA) and standard angiography (SA). **A:** overall pooled analysis. **B:** analysis stratified by independent reviewers. Effect sizes are expressed as mean difference (MD) with 95% confidence intervals (CI) using a fixed-effects model.

reduction in the radiation exposure time can be important to lower unwanted side effects caused by radiation. A previous meta-analysis including 1,916 patients reported a reduction of dose area product with a pooled MD of −10.40 Gycm^{-2} comparing DARCA with SA[18]. Finally, the DARCA method displayed a 56.5% reduction in exposure radiation for the operator[10].

Despite current data supporting the use of DARCA[8,18], some limitations can also be cited: (1) spatial limitations for operation; (2) untrained personnel; (3) lack of knowledge of this procedure; (3) the small number of impactful studies reporting DARCA diagnostic accuracy; and (4) lesions in the left main ostium and dumping or separate takeoff of left anterior descending artery and circumflex are difficult for DARCA[5,19].

Previous meta-analyses and several RCTs have demonstrated significant safety factors for patients undergoing DARCA rather than SA[6,20-23]. Despite the absence of significant articles comparing the diagnostic efficacy of DARCA for CAD diagnosis, SA remains the gold standard. However, SA has been shown to underestimate up to 33% of coronary lesion visualization and overestimate up to 6% when compared to autopsy and pathological studies, likely due to inadequate projections[6]. The reason why we believe this systematic review and meta-analysis can embase the consideration to implement DARCA even more.

This meta-analysis has limitations. Further assessment of the efficacy of DARCA, including sensitivity and specificity, was not possible due to the absence of confusion matrix elements in the included studies. In addition, the small number of head-to-head trials and the small overall sample size limit the meaning of performing a publication bias funnel plot and Egger's regression test. Finally, we believe that our study design could represent the first step toward truly representative data when comparing the diagnostic accuracy of DARCA to SA.

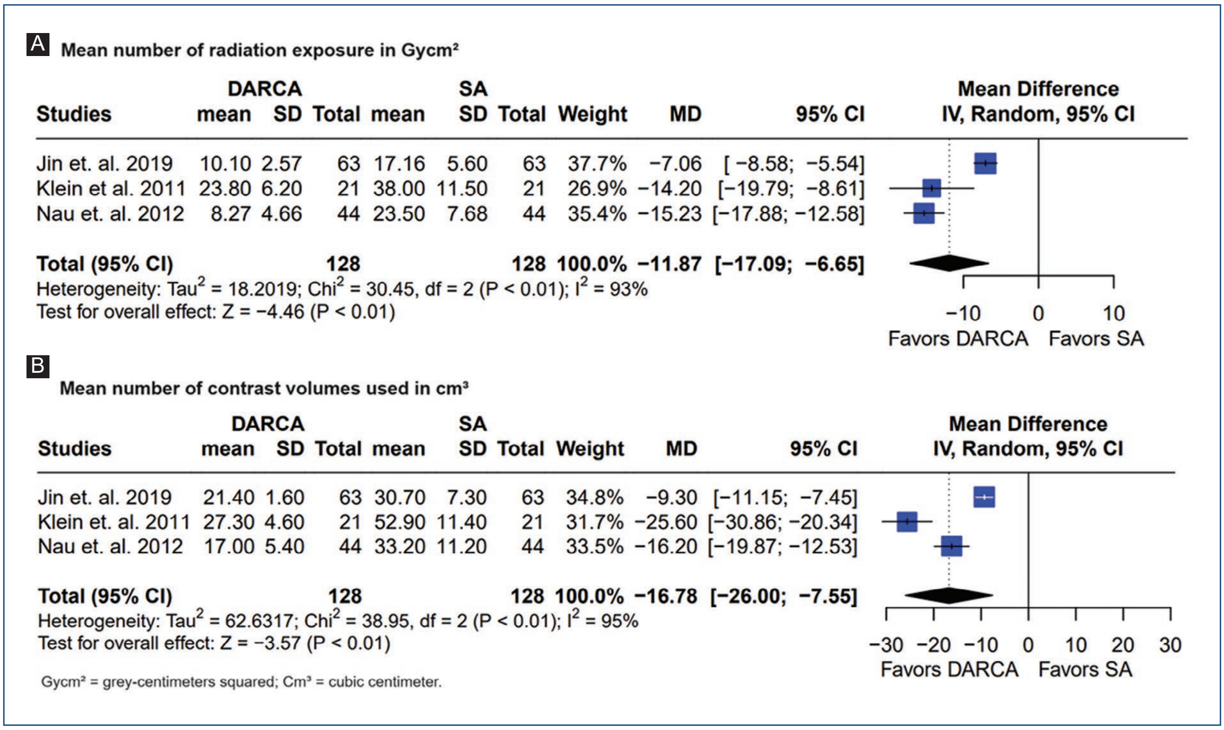

Figure 2. Forest plots comparing procedural parameters between dual-axis rotational coronary angiography (DARCA) and standard angiography (SA). **A:** radiation exposure (Gy·cm²). **B:** contrast volume (cm³). Effect sizes are expressed as mean difference (MD) with 95% confidence intervals (CI); fixed-effects model for radiation exposure and random-effects model for contrast volume.

Conclusion

This meta-analysis compared 128 patients with suspected CAD who underwent both DARCA and SA in a direct comparison manner. Regarding efficacy estimation, DARCA was demonstrated to be slightly superior to SA, the current Gold Standard, for determining coronary lesions. Further, radiation exposure measurements exhibited a substantial reduction when patients underwent DARCA. Finally, a significant benefit was identified with the use of DARCA for contrast dose reduction by both automatic systems for contrast injection and manual contrast injection. Our results could indicate that DARCA presents as a safer option for coronary visualization while maintaining similar diagnostic precisions when compared to SA.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare to have followed the ethical standards of the relevant experimentation committee, according to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from all patients, and secured approval from the Ethics Committee. SAGER guidelines have been followed as applicable to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

Supplementary data

Supplementary data are available at DOI: 10.24875/ACM.24000180. These data are provided by the corresponding author and published online for the benefit of the reader. The contents of supplementary data are the sole responsibility of the authors.

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