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Research article

Angiographic Complications Using a Medium or Small Initial Burr-to-Artery Ratio for Rotational Atherectomy

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Abstract

Objectives: In this prospective cohort study, we investigated the safety and efficacy of rotational atherectomy, comparing the use of an initial small with medium burr-to-artery ratio. **Background:** Rotational atherectomy (RA) is recommended in heavily calcified lesion preparation. Inadequate RA with a burr-to-artery ratio ≤0.6 is associated with increased rate of instent restenosis A burr-to-artery ratio > 0.7 is associated with an increased risk of immediate post-procedural angiographic complications Thus, selection of the initial burr size for RA remains debatable. **Methods:** We enrolled 73 patients and 76 RA procedures in three tertiary hospitals, with a 6-month follow-up. The primary endpoint was any serious intraprocedure or immediate post-RA angiographic complications occurring during or after the final RA run, including severe dissection, uncorrectable no-reflow phenomenon, coronary perforation, and burr entrapment (Kokeshi phenomenon). **Results:** We found no significant difference in the rate of serious complications between treatment groups with burr-to-artery ratio ≤0.6 and >0.6 (6.45% vs. 8.89%, p=1.00). Regarding the reason for considering RA, we found a trend of an increased rate of serious complications with unplanned versus planned RA (11.5% vs. 6.0%, p=0.33) or with inadequate lesion preparation (16.7% vs. 5.2%, p=0.14). **Conclusions:** For coronary lesions requiring RA, the rate of serious angiographic complications did not differ when using an initial burr size with a burr-to-artery ratio of ≤0.6 or >0.6.

Keywords: rotational atherectomy, angiographic complication, burr-to-artery ratio

Background

Coronary artery disease treatments, both in terms of medications and interventions, have undergone dramatic development, resulting in reduced mortality and prolonged

life expectancy in patients with coronary artery disease. However, some patients can eventually relapse, with much more complex lesions and coronary problems.

A major issue in dealing with complex coronary lesions involves dealing with heavy calcification. Initial plain balloon or cutting balloon predilatation may lead to inadequate preparation and failure of the procedure.[1] In such lesions, guidelines and expert consensuses recommend rotational atherectomy (RA) in lesion preparation.[2,3,7]

Regarding the initial burr size selection, Sharma et al. conducted a retrospective study to investigate those factors that are associated with instent restenosis (ISR) and target vessel revascularization (TVR). They found that inadequate RA with a burr-to-artery ratio ≤0.6 was associated with recurrent ISR (odds ratio 7.46).[4]Safian et al. performed the Coronary Angioplasty and Rotablator Atherectomy Trial (CARAT) prospective randomized trial, aiming to compare results between the "lesion debulking strategy" using a final burr-to-artery ratio >0.7 and the "lesion modification strategy" using a final burr-to-artery ratio ≤0.7. Those authors found that the former strategy led to more serious immediate post-procedural angiographic complications in comparison with the latter strategy (12.7% vs. 5.1%).[5] According to these results, expert consensuses recommend an initial burr-to-artery ratio of 0.5–0.6 and using a stepwise approach with respect to burr size until achieving adequate lesion preparation.[6,7] This approach seems safe but it could be costly if more than one burr is needed. Thus, there is no definite guideline to address the appropriate initial burr size and there is a gap in the evidence regarding whether an initial burr-to-artery ratio between 0.6 and 0.7 could be more appropriate.

Therefore, in this prospective cohort study, we aimed to investigate the safety and efficacy of RA, comparing an initial strategy using a small burr size and an initial strategy using a medium burr size.

Methods

Patient population

We collected data from three tertiary hospitals: Chulabhorn Hospital, Bangkok; Maharat Nakornratchasrima Hospital, Nakornratchasrima; and Police General Hospital, Bangkok. The patients were informed and consented to the use of clinical data, including medical records, laboratory results, and angiographic imaging. Documented data were reviewed for baseline characteristics. We recorded the reason for undergoing RA and the rotablator burr, and stent size and length used. The study protocol was approved by the ethics committee of each participating centers.

Endpoints

The primary endpoint was any serious intraprocedure or immediate post-RA angiographic complication occurring during or after the final run of RA that could lead to cardiogenic shock and immediate death. Such complications included severe dissection, uncorrectable no reflow phenomenon, coronary perforation, and burr entrapment (Kokeshi phenomenon).

The secondary endpoints were target vessel revascularization at 1 and 6 months, cardiac death at 1 and 6 months, initial burr-to-artery ratio, and total number of burrs used.

Definitions

Severe dissection was defined as dissection type D, E, and F. These types of dissection have high rates of abrupt vessel closure.[8] Uncorrectable no reflow phenomenon was defined as angiographic no reflow that cannot be corrected after attempt. Coronary perforation comprised perforation types 2 and 3. These types of coronary perforation are more likely to proceed to cardiac tamponade.[9] Burr entrapment was defined as any entrapment, retrievable or non-retrievable. The reason for RA was divided into three categories: uncrossable, planned RA owing to heavy calcification, and inadequate lesion preparation. Uncrossable was defined as only a wire with or without supporting microcatheter being able to cross the target lesion. Inadequate lesion preparation was defined as any predilatation to the target lesion before RA.

Study procedure and data handling

Baseline characteristic data were retrieved from the database from each participating centers, including underlying hypertension, diabetes, dyslipidemia, history of myocardial infarction or ischemic stroke, and peripheral arterial disease. Laboratory data were reviewed for the most recent values of creatinine and estimated glomerular filtration rate. The procedural equipment and technique used were at the operators' discretion. If percutaneous coronary intervention (PCI) was performed due to acute coronary syndrome in the same admission, the duration after symptom onset was rounded up and recorded in days. Angiograms were reviewed by one author to identify the index cine-loops, which were the cines of the appropriate view for target vessel revascularization.

The purpose of angiographic review was to search for angiographic complications during RA and immediately post-RA and to conduct quantitative coronary analysis (QCA) measurement for distal reference diameter. If QCA could not be done using a computational method, manual measurement was carried out using a catheter as the reference size. Distal reference diameters were rounded to full, half, or quarter diameters before documentation. Procedural logs were reviewed for the number of burrs used and stent deployments.

Clinical follow-up

Clinical follow-up was conducted by telephone at 1 and 6 months after the index procedure. If communication by telephone was not done, the patient database was reviewed to search for details regarding the follow-up visit.

Statistical analysis

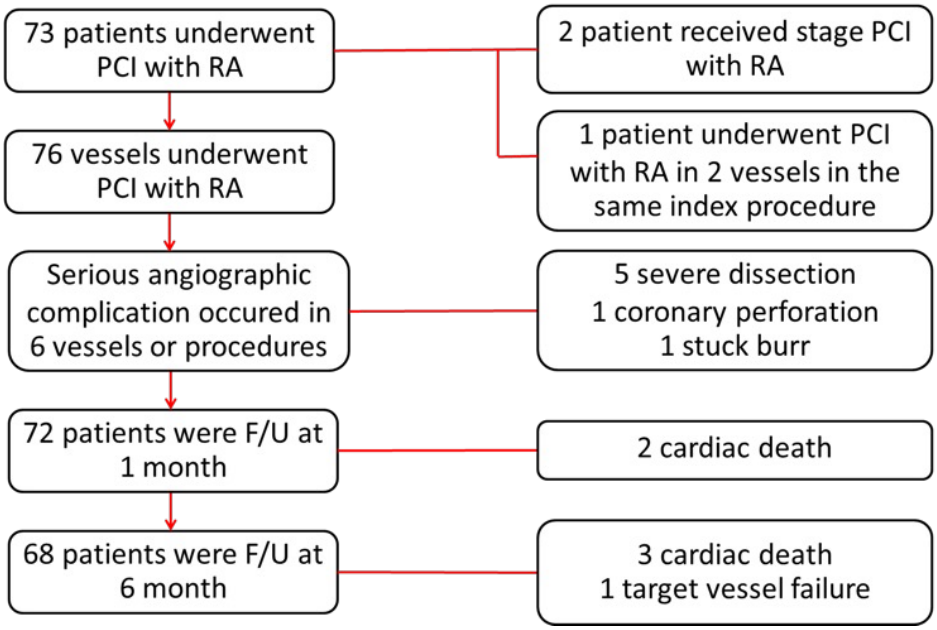
We estimated the sample size by inferring from the previous CARAT trial. Assuming that the average burr size commonly selected by most operators approached a burr-to-artery ratio of 0.6, according to European expert concensus10, and a burr-to-artery ratio of ≤0.6 and >0.6 was chosen equally, we would need to enroll at least 44lesions per group for the study to have 90% power to detect a rate difference in the primary endpoint, with 12.7% in the group with a burr-to-artery ratio of >0.6 and 5.1% in the group with a burr-to-artery ratio of ≤0.6, with a type I error rate of 5% (two-sided). Categorical data are expressed as percentage and compared using the chi-square test and Fisher's exact test. Continuous data are expressed as mean and standard deviation and compared using the Student t-test. Cumulative

incidence data were analyzed using Kaplan–Meier estimation. IBM SPSS version 25.0 was used for statistical analyses (IBM Corp., Armonk, NY, USA).

Results

Between July 1, 2020 and December31, 2021, we prospectively investigated 73 patients who underwent RA during PCI owing to any reason. Two RA procedures were performed during stage PCI. One patient received RA in both left anterior descending artery and left circumflex artery revascularization in the same index procedure. In total, we identified76 target vessel RA procedures. At 1 month after the index procedure, 72 patients were available for follow-up and 68 patients were available for follow-up at 6 months after the index procedure. Details are shown in **Figure 1**.

Figure 1. Study population and follow-up



PCI, percutaneous coronary intervention; RA, rotational atherectomy; F/U, followed up.

Baseline clinical characteristics

We included 73 patients with 76 RA procedures in our study. Baseline characteristics are shown in **Table 1.** There were no significant differences in baseline characteristics except for underlying diabetes (35.5% in burr-to-artery ≤0.6 ratio vs. 42.9% in burr-to-artery >0.6 ratio groups, p=0.019)

Table 1. Baseline characteristics

	Total (73 patients, 76procedures)	**Burr-to-artery ratio ≤0.6 (31 patients, 31 procedures)**	**Burr-to-artery ratio >0.6 (42 patients, 45 procedures)**	**p-value**
Age (y)	70.6±7.8	71.8±7.8	69.7±7.9	0.261
Men (%)	56.6	67.7	52.4	0.157
Diabetes (%)	52.6	35.5	64.3	0.019
Hypertension (%)	81.6	77.4	83.3	0.550
Dyslipidemia (%)	39.5	35.5	42.9	0.636
Previous MI (%)	48.7	45.2	47.6	0.647
PAD (%)	1.3	0	2.4	1.000
Old CVA (%)	15.8	16.1	14.3	1.000
CKD (%) - eGFR <50 (mL/min/1.73m^2) - ESRD	 37.3 8.0	 36.7 10.0	 38.1 7.1	 1.000 0.678
ACS on presentation (%) - PCI within 72 h of onset	31.6 14.5	32.3 22.6	28.9 13.3	0.619 0.359

CKD, chronic kidney disease; eGFR,estimated glomerular filtration rate; ACS, acute coronary syndrome; PCI, percutaneous coronary intervention; PAD, peripheral artery disease; MI, myocardial infarction; CVA, cerebrovascular accident; ESRD, end-stage renal disease.

Baseline angiographic characteristics

The mean and median of the distal reference diameter were 2.36 mm and 2.25 mm, respectively. The most frequently used initial burr size was 1.5 mm (68.4%), followed by 1.25 mm (23.7%); the least-used burr size was 1.75 mm (7.9%). The reasons to consider RA were mostly owing to heavy calcification with planned RA (65.8%), followed by inadequate lesion preparation after predilatation (23.7%) and uncrossable lesion (10.5%). Details are shown in **Table 2.** and **Supplementary Figure 1.**

Table 2. Baseline angiographic characteristics

	Total	Burr-to-artery ratio ≤0.6	Burr-to-artery ratio >0.6	p-value
Distal reference diameter (mm)	2.36±0.44	2.77±0.34	2.08±0.23	<0.001
Initial burr size (n, %) 1.25 1.5 1.75	 18 (23.7) 52 (68.4) 6 (7.9)	 8 (25.8) 20 (64.5) 3 (9.7)	 10 (22.2) 32 (71.1) 3 (6.7)	0.808
Reason for RA (%) Uncrossable Planned RA owingto heavy calcification Inadequate lesion preparation	 10.5 65.8 23.7	 6.5 77.4 16.1	 13.3 57.8 28.9	0.206

Study end points

From 76 target vessel RA procedures, any serious intraprocedural or immediate post-RA complications occurred in six (7.9%) procedures. The average initial burr-to-artery ratio was 0.64. Distal reference vessels in the group with burr-to-artery ratio ≤0.6 were larger than in the group with burr-to-artery ratio >0.6 (2.77±0.34 mm vs. 2.08±0.23 mm, p<0.001). Most procedures could be carried out using a single burr in the groups with burr-to-artery ratio ≤0.6 and >0.6 (93.5% vs. 91.3%). There was no significant difference in the rate of serious complications between treatment groups with burr-to-artery ratio ≤0.6 and >0.6 (6.45% vs. 8.89%, p=1.00). When comparing the reasons to consider RA, there was a trend of an increased rate of serious complications if RA was an unplanned procedure (11.5% vs. 6.0%, p=0.33) or after inadequate lesion preparation (16.7% vs. 5.2%, p=0.14). There was no significant difference in the rate of cardiac death and target vessel revascularization between treatment groups with follow-up at 6 months. We found no interaction between the initial burr-to-artery ratio and total number of burrs used. Details are shown in **Table 3.** and **Figures 2–5.**

Table 3. Results

	Total	Burr-to-artery ratio ≤0.6	Burr-to-artery ratio >0.6
Serious complication (n, %) Severe dissection No reflow Coronary perforation Stuck burr	6 (7.9) 5 (6.6) 1 (1.3) 0 1 (1.3)	2 (6.5) 2 (6.5) 0 0 0	4 (8.9) 3 (6.7) 1 (2.2) 0 1 (2.2)
Average burr-to-artery ratio	0.64±0.11	0.53±0.06	0.71±0.07
Total burrs used (n, %) 1 burr 2 burrs 3 burrs	 70 (92.1) 5 (6.6) 1 (1.3)	 29 (93.5) 1 (3.2) 1 (3.2)	 42 (91.3) 4 (8.3) 0
Cumulative cardiac death at 1 months (n, %) Cumulative cardiac death at 6 months (n, %)	2 (2.6) 5 (6.6)	1 (3.2) 2 (6.5)	1 (2.2) 3 (6.7)
Cumulative target vessel revascularization at 1 month (n, %) Cumulative target vessel revascularization at 6 months (n, %)	0 1 (1.3)	0 0	0 1 (2.2)

Figure 2. Events of primary outcome and burr-to-artery ratio

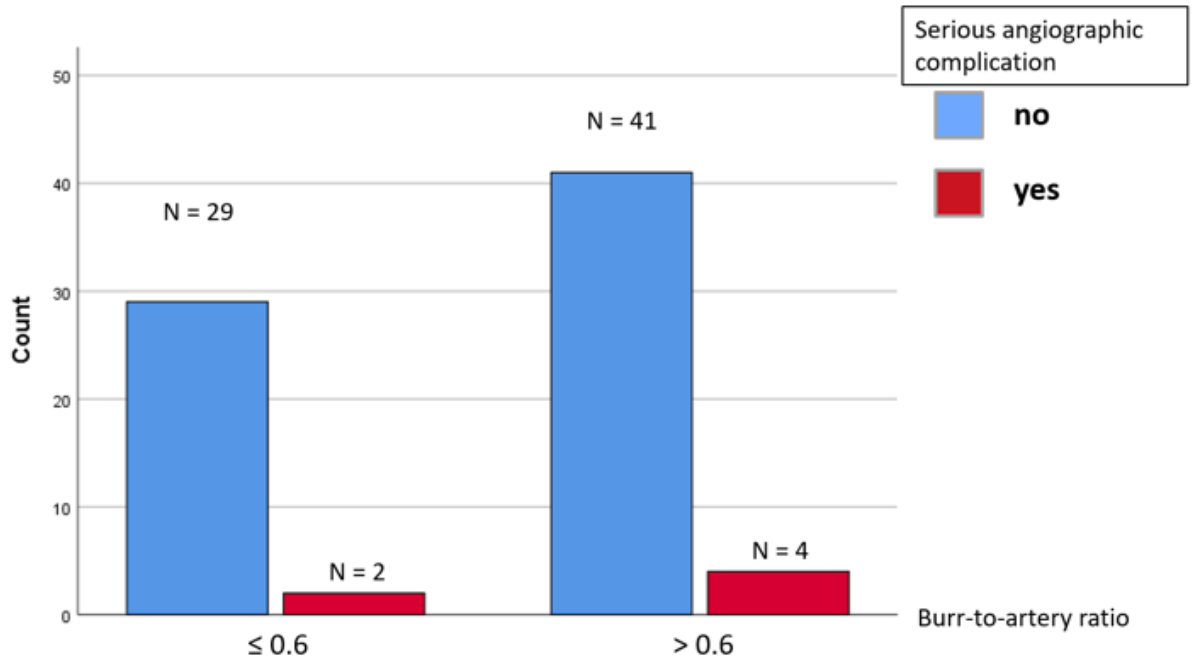


Figure 3. Events of primary outcome and reasons for rotational atherectomy (RA)

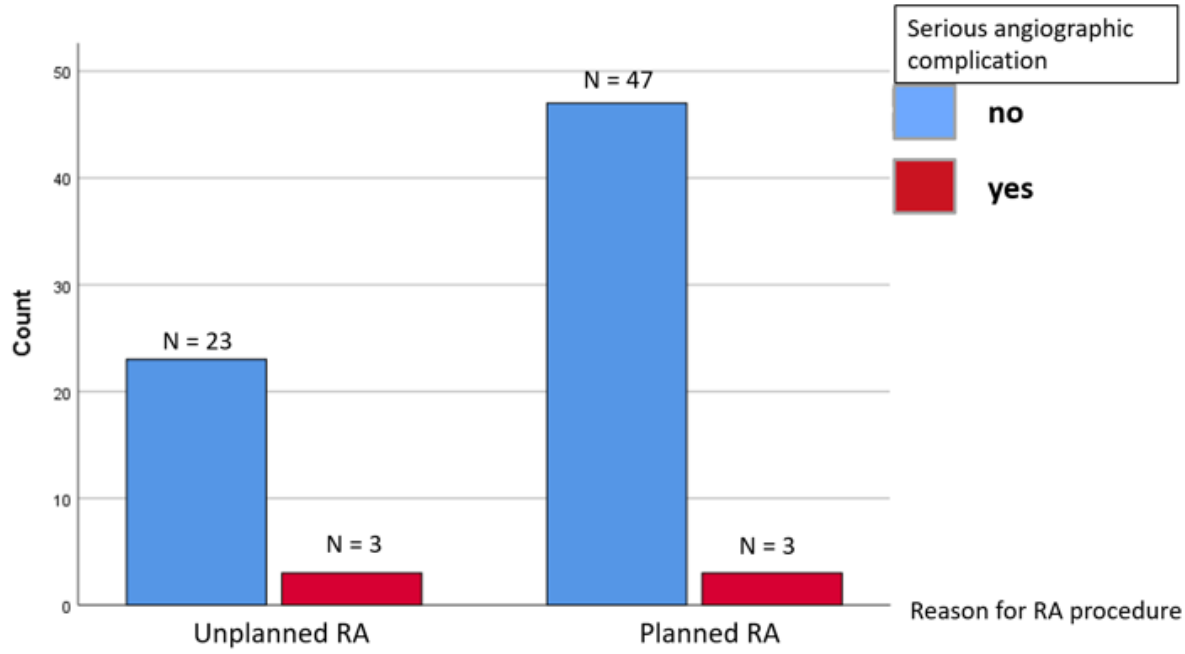


Figure 4. Events of primary outcome and reason for rotational atherectomy (RA) owing to inadequate lesion preparation or other reason

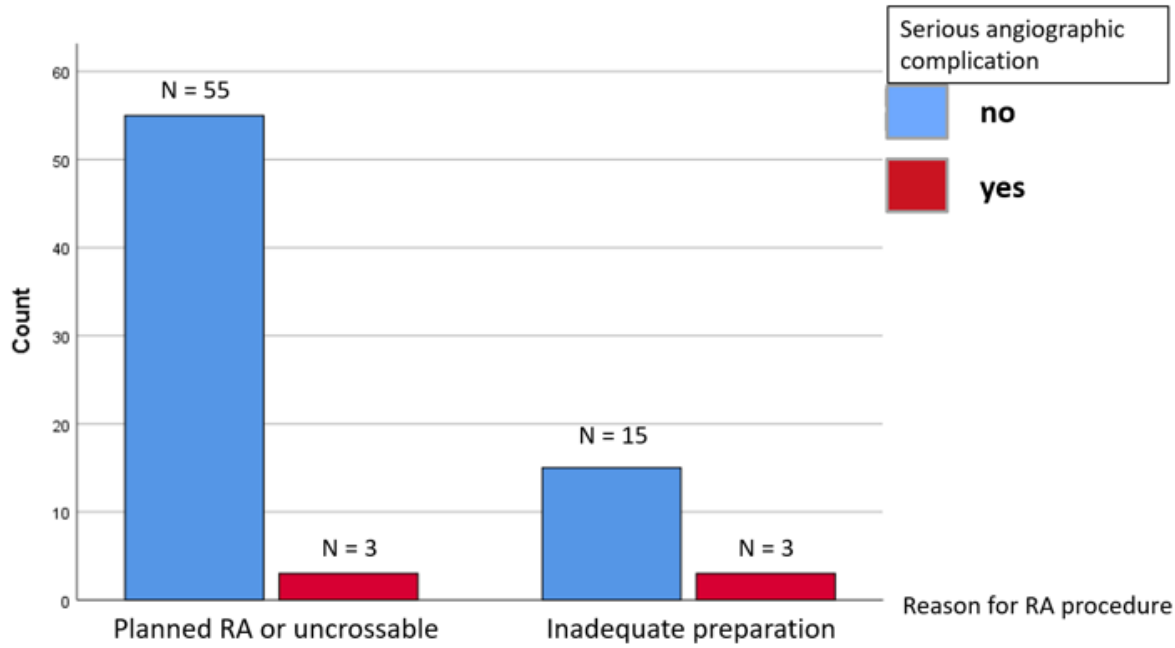
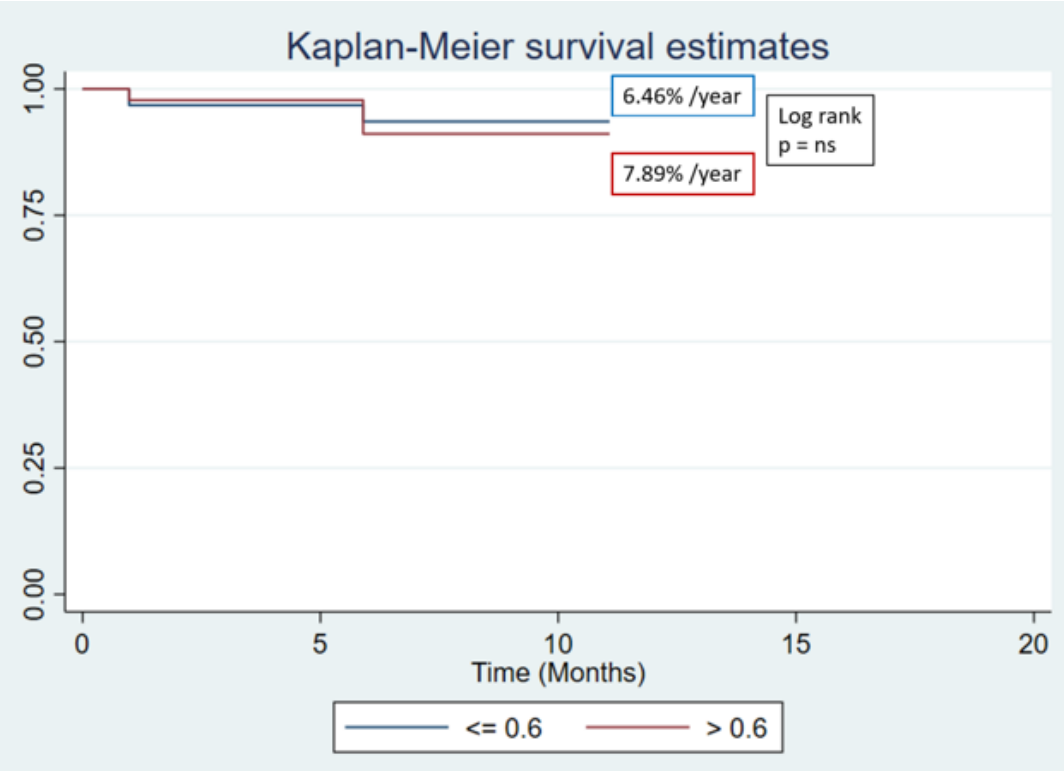


Figure 5. Overall survival by burr-to-artery ratio



Discussion

There are two main findings in this contemporary RA cohort trial. First, there was no difference in the rate of serious angiographic complications using a burr-to-artery ratio of ≤0.6 or>0.6. Second, there was no significant difference in the rate of cardiac death and target vessel revascularization between treatment groups during the 6-month follow-up.

Regarding the different time points in this trial, we found rates of serious complications owing to RA that were similar to those of the CARAT trial. This could reflect the fact that a substantial risk remains in RA despite conducting the procedure in our practice for decades. Despite the risk with the procedure, RA is unavoidable in a large proportion of lesions, as reflected in this trial where23.7% of lesions required RA owing to inadequate lesion preparation and 10.5% required RA owing to an uncrossable lesion. Additionally, many lesions in ACS require RA within 72 hours, which is classified as a relative contraindication. Most lesions in this study were adequately prepared using a single burr and we mostly used a 1.5 mm burr, which corresponds to the recommendations of expert consensuses. Our trial showed a trend of an increased rate of serious complications if RA was unplanned, especially if RA was done after predilatation. Although this finding did not reach statistical significance, it should be emphasized that a pre-stenting strategy is important and should be properly planned before tackling the target lesion. Intravascular imaging is also key, adding crucial information in uncertain cases in addition to angiographic evaluation alone.

This trial has several limitations. First, there was an inadequate sample size in the 2-year time frame of this study. Second, the baseline characteristics were incomplete, including important information such as complexity of the lesions, intravascular imaging information, and clinically important history such as prior PCI or coronary artery bypass grafting. More robust data collection will help to clarify causal relationships in the success or failure of RA. Third, this was a prospective cohort trial and important confounding factors could affect the results.

In conclusion, in the context of coronary lesions requiring RA, the rate of serious angiographic complications was not different between groups using a burr size with burr-to-artery ratio ≤0.6 and >0.6.

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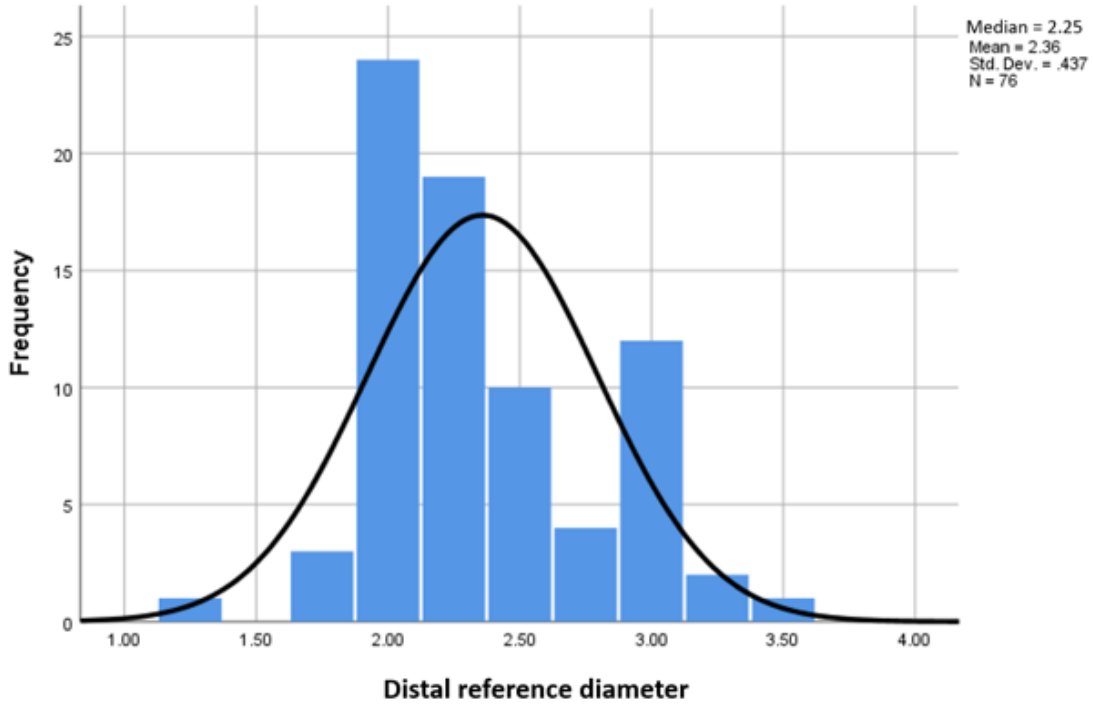
Supplementary data

Figure 1. Distal reference diameter



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