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Clinical outcomes of PCI with rotational atherectomy: the European multicentre Euro4C registry

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KEYWORDS

- atherectomy
- calcified stenosis
- left main
- multiple vessel disease
- rotablator
- undilatable lesion

Abstract

Aims: Despite the use of rotational atherectomy (RA) in interventional cardiology for over three decades, data regarding factors affecting the clinical outcomes of the RA procedure remain scarce. The aim of the present study was to describe the contemporary use and outcomes of RA in Europe.

Methods and results: We conducted, for the first time, a prospective international registry in 8 European countries and 19 centres and included patients treated by percutaneous coronary intervention with RA. Between October 2016 and July 2018, 966 patients with complete data were recruited. Mean age was 74.5 years, 72.4% were male and 43.4% had diabetes. Initial presentation was an acute coronary syndrome (ACS) for 25.1% of the patients. Clinical success was observed in 91.9% of the procedures. The rate of in-hospital major adverse cardiac events (MACE) – defined as cardiovascular death, myocardial infarction, target lesion revascularisation, stroke and coronary artery bypass grafting – was 4.7%. At one year, the rate of MACE was 13.2%. Factors independently associated with the occurrence of MACE at one year were female gender, renal failure, ACS at admission, depressed left ventricular ejection fraction (LVEF) and presence of a significant left main coronary artery (LMCA) lesion.

Conclusions: Despite the high level of complexity of the studied population, RA turned out to be an effective procedure with a low rate of in-hospital complications and demonstrated good immediate and midterm results.

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Abbreviations

BMI	body mass index
BMS	bare metal stent
BRS	bioresorbable scaffold
CABG	coronary artery bypass grafting
CAD	coronary artery disease
CTO	chronic total occlusion
DES	drug-eluting stent
GFR	glomerular filtration rate
HR	hazard ratio
LMCA	left main coronary artery
LVEF	left ventricular ejection fraction
MACE	major adverse cardiac events
MDRD	Modification of Diet in Renal Disease
MI	myocardial infarction
NSTEMI	non-ST-elevation myocardial infarction
PCI	percutaneous coronary intervention
RA	rotational atherectomy
STEMI	ST-elevation myocardial infarction
TIA	transient ischaemic attack

Introduction

With the expansion of percutaneous coronary intervention (PCI) indications to more challenging anatomies, and considering the ageing of the population, the proportion of patients with calcified coronary lesions treated by PCI has increased over the past decade. Nowadays, around 20% of patients who are candidates for PCI present with moderate to severe coronary calcifications[1]. In spite of technological advances, PCI of complex calcified coronary lesions remains a challenge. Indeed, coronary calcification increases the technical difficulties of the procedure, hampering the delivery and expansion of coronary angioplasty balloons and stents, leading to stent underexpansion or malapposition: both conditions increase the risk of in-stent restenosis and thrombosis[2]. Moreover, coronary calcification also increases the risk of dissection[3] and perforation[4] during PCI.

Rotational atherectomy (RA) is an adjunctive tool in the armamentarium of interventional cardiologists introduced in 1987 for the treatment of calcified coronary lesions[5]. In Europe, RA is used in 0.8 to 3.1% of PCI[6]. The principle of this device is to ablate the calcified atherosclerotic coronary plaque by advancing a high-speed diamond-incrusted elliptical burr in the vessel. RA is nowadays performed to achieve "plaque modification", using small burrs that facilitate optimised stenting. Randomised trials have demonstrated that an aggressive debulking (i.e., a burr/vessel ratio >0.70) yielded no benefits in terms of procedural success or target lesion revascularisation (TLR) and was associated with more immediate complications[7,8]. Thus, in most RA procedures, the passage of the burr in the vessel allows the deliverability of a coronary balloon followed by a stent implantation.

However, although RA has been performed for over three decades, data regarding the contemporary use of this technique in daily practice, and its clinical outcomes, remain scarce. We conducted, for the first time, a prospective multicentric international observational registry of patients treated by PCI with RA in order to describe the contemporary use and outcomes of RA in Europe.

Editorial, see page 269

Methods

STUDY DESIGN AND POPULATION

The Euro4C registry was a prospective, observational and multicentric European registry conducted in 19 centres, based in eight European countries (France, Poland, Germany, Spain, Italy, Greece, Austria and Russia). Patients included in the study were aged 18 or older and were treated with coronary PCI using RA for at least one lesion, between October 2016 and July 2018. The decision to use RA was left to the discretion of the operator. The study protocol was approved by the institutional review board of each participating centre and all patients gave their written consent to participate in the study. Follow-up was performed by phone call at day 30 and at one year.

DATA COLLECTION

Data at baseline and during follow-up were collected through an electronic case report form (e-CRF). Initial clinical presentation and angiographic data describing the topography and the extent of the coronary disease were recorded.

ROTATIONAL ATHERECTOMY PROCEDURE

RA procedures were performed using the Rotablator™ system (Boston Scientific, Marlborough, MA, USA). Characteristics of the RA procedure were extensively recorded. According to the definition of the European Bifurcation Club consensus[9], a lesion was considered a bifurcation lesion if occurring at, or adjacent to, a significant division of a major epicardial coronary artery. In this study, RA, in a calcified bifurcation lesion, could be used in any segments, single or combined, of the bifurcation. The technical parameters of rotablation were accurately recorded. Patients were treated exclusively with drug-eluting stents (DES) in 98.2% of cases.

OUTCOMES

The primary endpoint was defined as a composite of the cumulative incidence of cardiovascular death, myocardial infarction (MI), TLR, stroke and coronary artery bypass grafting (CABG) up to one year following the procedure.

The secondary endpoints were the clinical success rate of the RA procedure (defined as a successful revascularisation of all treated lesions [residual stenosis <50%] and no periprocedural complications) and the incidence of in-hospital complications including coronary perforation, coronary dissection, coronary low flow or no flow, emergency CABG, tamponade, MI, stroke or transient ischaemic attack (TIA), bleeding events (according to the Bleeding Academic Research Consortium [BARC] classification[10]) and death.

Detailed definitions of these endpoints are presented in **Supplementary Appendix 1**.

STATISTICAL ANALYSIS

Statistical analysis was performed using Stata statistical software, release 14.1 (StataCorp, College Station, TX, USA). Continuous variables were summarised as means and standard deviations for normal distribution, and as medians and interquartile ranges when not normally distributed. Categorical variables are presented as proportions. In order to identify factors associated with the occurrence of the primary and secondary endpoints, differences between groups were tested using the chi-square test for qualitative data and means comparisons for continuous data. Non-parametric tests were used when necessary. Multivariate analyses were performed using logistic regression and the Cox model.

Results

Between October 2016 and July 2018, 1,016 consecutive patients were included in the study. The distribution of patients according to their country of inclusion is shown in **Supplementary Table 1**. Fifty patients were excluded because of missing data; thus, 966 patients were included in the final analysis. The follow-up was complete for 950 patients (98.3%) and 891 patients (92.2%) at 30 days and one year, respectively.

BASELINE PATIENT CHARACTERISTICS

Mean age was 74.5 years and 72.4% were male. The presentation was stable for 64.1% of the patients, 4.2% presented with ST-elevation myocardial infarction (STEMI), 20.9% with non-ST-elevation myocardial infarction (NSTEMI) and 10.8% with unstable angina. Baseline clinical features are summarised in **Table 1**.

BASELINE ANGIOGRAPHIC CHARACTERISTICS

Two hundred and forty-one patients (25%) presented with a significant lesion (i.e., ≥50%) on the left main coronary artery (LMCA), 368 (38.1%) had three-vessel disease, and 280 (29%) had a chronic total occlusion of an epicardial coronary trunk (treated or not with RA). Baseline angiographic characteristics are described in **Table 2**.

ROTATIONAL ATHERECTOMY PROCEDURE

The vascular approach was radial for 71.8% of procedures, and the sheath size <7 Fr in 75.1% of cases. Only one lesion was treated with RA in 725 patients (75%). When several lesions were treated with RA, one single procedure was sufficient in 86% of cases. Regarding the rotablation itself, the maximal burr size was 1.5 mm in 51.7% of cases and the maximal burr speed was set between 160,000 and 180,000 rpm in 55.9% of procedures. Intracoronary imaging guidance by intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was used in only 6.9% of procedures. RA procedure characteristics are detailed in **Supplementary Table 2**. Procedural characteristics according to the country of inclusion (for countries which included a minimum of 30 RA procedures) are summarised in **Figure 1**.

Table 1. Baseline clinical characteristics of the population.

Baseline characteristics		N	(%)
Male gender		699/966	72.4
Age, years*		74.5	±9.8
Diabetes mellitus		415/956	43.4
Hypertension		792/965	82.1
Dyslipidaemia		689/962	71.6
Active tobacco use		162/846	19.2
Obesity, BMI >30 kg/m²		217/953	22.8
Peripheral vascular disease		219/966	22.7
Previous stroke or TIA		128/958	13.4
Previous MI		276/959	28.8
Previous PCI		408/964	42.3
Previous CABG		139/965	14.4
MDRD creatinine clearance, ml/min/1.73 m²	<30	70	7.4
	30-59	258	27.3
	≥60	616	65.3
Killip class	I-II	700	96.7
	III-IV	24	3.3
Haemoglobin, gr/dl *		12.9	±2.1
Clinical presentation	STEMI	40	4.2
	NSTEMI	202	20.9
	Unstable angina	104	10.8
	Stable angina or silent ischaemia	619	64.1
LVEF, %	≤35	139	16.5
	35-49	213	25.3
	≥50	489	58.2

* Mean±SD. BMI: body mass index; CABG: coronary artery bypass grafting; LVEF: left ventricular ejection fraction; MI: myocardial infarction; MDRD: Modification of Diet in Renal Disease; NSTEMI: non-ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; SD: standard deviation; STEMI: ST-elevation myocardial infarction; TIA: transient ischaemic attack

IN-HOSPITAL OUTCOMES

The rate of clinical success, defined as an angiographic success and no post-procedure complications within 24 hours, was 91.9%. In-hospital major adverse cardiac events (MACE) occurred in 45 patients (4.7%). Rates of death and post-procedure MI were 1.6% and 2.9%, respectively. Coronary perforation occurred in 16 patients (1.7% of cases), leading to a cardiac tamponade in five patients (0.5%). No cases of emergency CABG were recorded.

Table 2. Baseline angiographic characteristics of the population.

Angiographic characteristics		N	(%)
Left main coronary artery stenosis		241/966	25.0
Number of diseased vessels	1	229	23.7
	2	369	38.2
	3	368	38.1
Calcified bifurcation		359/965	37.2
Chronic total occlusion		280/966	29.0

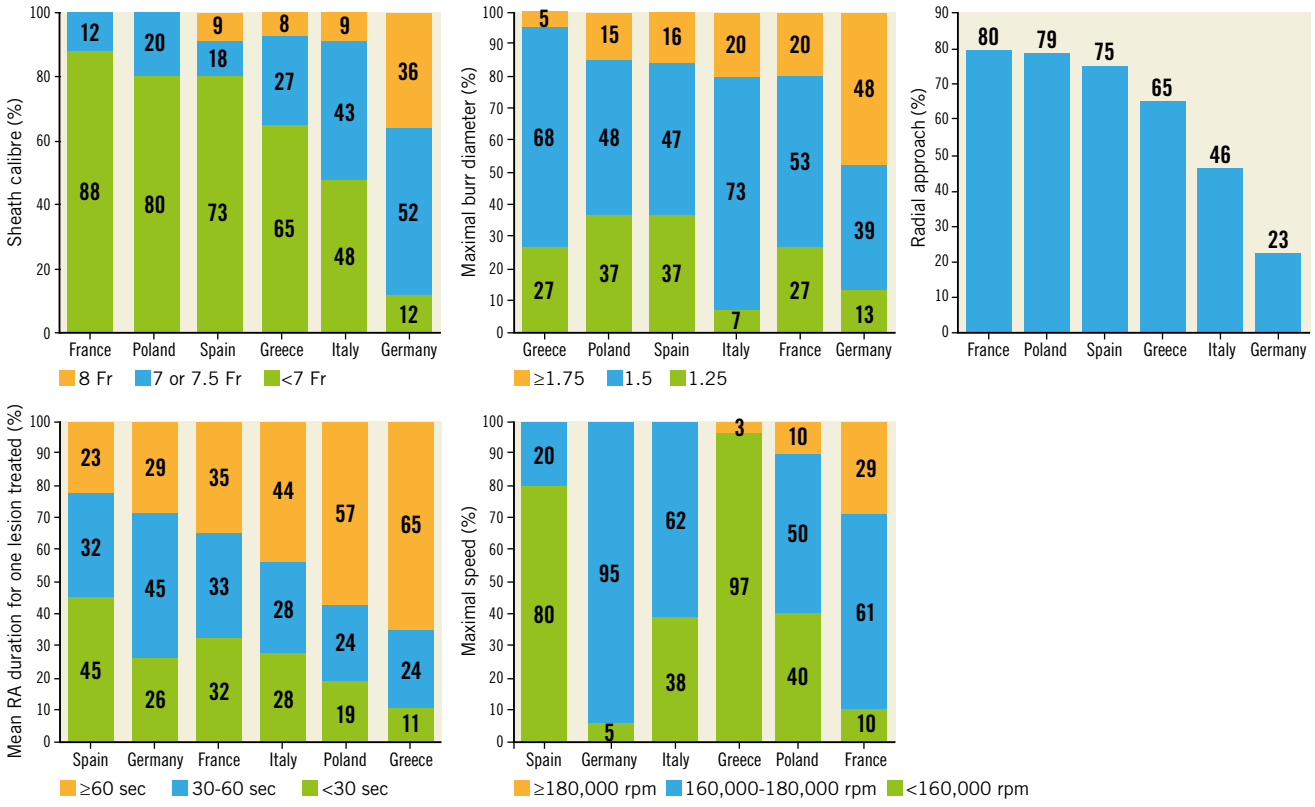

Figure 1. *Technical characteristics of the RA procedure according to the country of inclusion.*

Severe bleeding (BARC ≥3) occurred in 12 patients during hospitalisation. No differences were observed between radial and femoral access (7 patients [1%] in the radial group vs 5 patients [1.8%] in the femoral group, p=0.33). Among patients treated by femoral approach who presented a bleeding, no differences were found according to the size of the sheath (2 subjects [1.6%] in the <7 Fr group vs 3 subjects [2.1%] in the ≥7 Fr group, p=1.00). In-hospital outcomes are summarised in **Table 3**.

Table 3. In-hospital outcomes.

In-hospital outcomes	N	(%)
Clinical success	885/963	91.9
MACE	45/966	4.7
Death	15/965	1.6
Myocardial infarction	28/965	2.7
Stroke or TIA	3/965	0.3
Perforation	16/965	1.7
Dissection	38/965	3.9
Low flow/no flow	12/965	1.2
Emergency CABG	0/965	0.0
Tamponade	5/965	0.5
Bleeding, BARC ≥3	12/966	1.2

CABG: coronary artery bypass grafting; BARC: Bleeding Academic Research Consortium; MACE: major adverse cardiac events; TIA: transient ischaemic attack

MEDICAL THERAPY AT DISCHARGE

Nine hundred and three patients (96.6%) had dual antiplatelet therapy (DAPT) at discharge and 188 (20.1%) had an oral anticoagulant therapy. Beta-blockers and statin therapy were prescribed to 81.7% and 88.5% of patients, respectively. The medical treatment prescribed at discharge is detailed in **Supplementary Table 3**.

FOLLOW-UP OUTCOMES

The rate of MACE (defined as cardiovascular death, MI, stroke or TIA, TLR or CABG) was 5.6% and 13.2% at 30 days and one year, respectively. The rate of all-cause death was 2.5% at 30 days (2.1% for cardiovascular death) and 9.7% at one year (5.7% for cardiovascular death). The 30-day and one-year outcomes are detailed in **Table 4**.

PREDICTORS OF MACE

Multivariate analysis identified Killip class III/IV (odds ratio [OR] 4.86, confidence interval [CI]: 1.47-16.10; p=0.010) and LMCA stenosis (OR 2.66, CI: 1.38-5.12; p=0.003) as predictors of in-hospital MACE, whereas past medical history of CAGB remained associated with a "protective" effect (OR 0.21, CI: 0.05-0.91; p=0.037) **(Supplementary Table 4)**.

At 30 days, the multivariate analysis identified Killip class III/IV (OR 2.99, CI: 1.05-8.56; p=0.041), acute coronary syndrome (ACS) (OR 2.12, CI: 1.20-3.75; p=0.010) and a number of burr runs ≥3 (OR 4.27, CI: 1.03-17.70; p=0.046) as predictors of 30-day MACE **(Supplementary Table 5)**.

Table 4. 30-day and 1-year outcomes.

Outcomes	30-day outcomes		1-year outcomes		
	N	(%)	N	(%)	Incidence rate (for 100 person-years)**
MACE*	54/966	5.6	127/966	13.2	15.9 (13.4-18.9)
All-cause death	24/966	2.5	94/966	9.7	11.1 (9.1-13.6)
Cardiovascular death	20/966	2.1	55/966	5.7	6.5 (5.0-8.5)
Myocardial infarction	28/966	2.9	45/966	4.7	5.6 (4.1-7.4)
Target lesion revascularisation	3/966	0.3	23/966	2.4	2.8 (1.8-4.1)
Stroke	4/966	0.4	8/966	0.8	1.0 (0.5-1.9)
CABG	2/966	0.2	5/966	0.5	0.6 (0.2-1.4)
Target vessel revascularisation ***	5/966	0.5	33/966	3.4	4.0 (2.8-5.6)
Bleeding (BARC ≥3)	12/966	1.2	29/966	3.0	3.4 (2.3-4.9)

*Cardiovascular death, MI, stroke/TIA, TLR or CABG; **95% confidence interval; ***TLR or TVR. BARC: Bleeding Academic Research Consortium; CABG: coronary artery bypass grafting; MACE: major adverse cardiac events; MI: myocardial infarction; TIA: transient ischaemic attack; TLR: target lesion revascularisation; TVR: target vessel revascularisation

At one-year follow-up, the factors independently associated with the occurrence of MACE at one-year follow-up were female gender (OR 1.70, CI: 1.18-2.47; p=0.005), glomerular filtration rate (GFR) <30 ml/min/1.73 m² (OR 1.77, CI: 1.01-3.12; p=0.048), ACS at admission (OR 1.59, CI: 1.09-2.31; p=0.016), depressed left ventricular ejection fraction (LVEF) <35% (OR 1.61, CI: 1.02-2.55; p=0.040), and LMCA stenosis (OR 1.62, CI: 1.12-2.35; p=0.011) **(Figure 2, Supplementary Table 6)**.

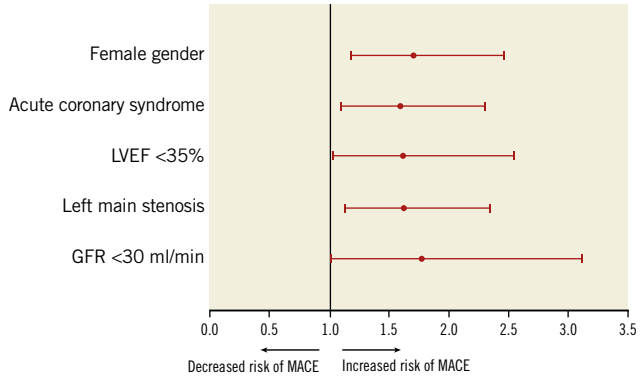

Figure 2. *Independent predictors for midterm major adverse cardiovascular events.*

Discussion

The Euro4C registry is the first international multicentric prospective registry investigating prognostic factors of clinical outcomes in PCI with RA. The main findings of this observational study are the following.

1. The rate of clinical success of RA was high and the rate of in-hospital complications was low, with a rate for in-hospital MACE of 4.9%.
2. The one-year rate of MACE was 13.2%, probably reflecting the high-risk level of patients rather than the consequences of the RA procedure itself.
3. The factors independently related to the occurrence of one-year MACE are common clinical factors in coronary artery disease (CAD), e.g., renal failure, ACS at admission, low LVEF, and LMCA stenosis. Interestingly, female gender was also independently associated with worse midterm outcomes.

This registry allows the assessment of the current practice and use of RA in experienced European centres. It is noteworthy that the radial approach was chosen in 71.8% of cases. This preferential vascular approach is in line with the highest standards of care and is in contrast with the largest available registry conducted on RA to date, the retrospective ROTATE registry, performed between 2002 and 2013, in which the femoral approach was used in 71.6% of cases[11]. The high rate of radial approach in our study allowed a wide use of 6 Fr guiding catheters (75.1% of procedures with sheaths ≤6 Fr), with burrs of up to 1.75 mm used in nearly 80% of the procedures reported. This preferential utilisation of small burrs is in line with the concept of plaque modification described previously. Although the access site was not independently related to short and midterm MACE in our cohort, it is well known that the radial approach allows a reduction of access site-related complications in PCI[12,13].

The low flow and no flow rate was relatively low in our cohort (1.2%). As centres participating in the study are very familiar with RA, this probably reflects that the procedures were carried out in accordance with a recent expert consensus document[6] which recommends using small burrs, short runs of ablation, speed of rotation below 180,000 rpm, pecking motion of the burr against the plaque, and liberal use of intracoronary nitrates between runs.

A certain degree of disparity among countries regarding the technical approach of RA was observed, although these disparities were not independently related to midterm outcomes. Similarly, such technical parameters were not identified as independent predictors of MACE in previous studies[11,14]. However, it is noteworthy in the present study that a number of runs >3 was independently associated with the occurrence of MACE at 30 days (hazard ratio [HR] 4.27, p=0.046), and a trend was noticeable for in-hospital MACE.

This finding might be explained by the presence of more severe or widened calcifications – requiring a higher number of runs to obtain a satisfactory debulking – responsible for a higher MACE rate.

The one-year MACE rate observed in this registry was 13.2%, mainly related to cardiovascular death (5.7%) and MI (4.7%). In a recent meta-analysis that pooled 18,441 subjects included in 18 trials treated by PCI with DES, Kedhi et al reported a one-year MACE rate of 9.4% and 13.9% for patients without and with diabetes, respectively[15]. Thus, the outcomes of this study appear acceptable when considering the high anatomical and clinical complexity of the recruited patients. Moreover, these outcomes are concordant with previous registries focusing on RA. In the Melbourne Interventional Group registry[16], the ROTATE registry[11], and in the Mount Sinai Hospital cohort[17], the one-year MACE rates were 15.6%, 16%, and 21.6%, respectively. The improvement observed in our study could, at least partially, be the result of a greater use of second-generation DES (98.2% vs 69.3% in ROTATE). In the ROTATE study, the MACE rate at one year was mainly driven by TLR (11.3%), whereas this rate was much lower in our cohort (2.4%), which appears to be a good result for such complex lesions.

Interestingly, in our study, female gender was independently associated with the occurrence of one-year MACE. To date, only one study has addressed the question of gender difference in outcomes following RA[18]. In this Scottish retrospective monocentric cohort that included 765 subjects treated with RA, the authors reported a similar incidence of MACE between female and male patients at 4.5-year follow-up, but a higher rate of procedural and in-hospital complications among females. In our cohort, we observed the same phenomenon in disfavour of female patients regarding in-hospital MACE (OR 1.87 [1.01-3.47]; p=0.047). Just as in this recent report, we observed a tendency, although non-significant, towards a higher number of perforation and dissection events in female patients (data not shown). These events explain the differences observed between male and female subjects in procedural outcomes, and are probably, at least partially, due to smaller-sized and more fragile arteries in women.

ACS as the initial presentation is, in the present study, related to the occurrence of one-year MACE. This result was expected, as ACS is known to have a worse prognosis than stable presentation of coronary disease, with, in particular, a high rate of events in the year following the ACS[19,20]. Previous studies have assessed the use of RA in the context of ACS[21,22]. They demonstrated that RA is feasible in this setting with safety outcomes similar to those in the context of stable CAD, but worse outcomes at midterm follow-up. Renal failure was also identified as an independent predictor of one-year MACE in our registry. This finding is consistent with the literature, as kidney disease is known to be a strong prognostic factor in CAD in general[23,24], and in particular in patients treated by RA[11,14]. Unsurprisingly, depressed LVEF and LMCA stenosis (treated with RA or not) were independently associated with the occurrence of MACE at one year. The prognostic importance of these simple parameters in CAD was first described four decades ago in the CASS registry[25] and has been confirmed since then, despite the critical advances achieved in the management of this pathology.

Limitations

The main limitation of this study is its observational design. The decision to use RA was left to the discretion of each centre and no central core lab analysed the procedures for endpoint definition. Thus, no preprocedural or post-procedural systematic quantitative coronary angiography (QCA) analysis was performed. Data regarding the global complexity of the coronary anatomy and on the level of risk of the patients in our population were not available.

Conclusions

Our study, focused on the contemporary approach of rotational atherectomy, demonstrates that this technique is safe and efficient, with low procedural and hospital complications and a high clinical success rate. During follow-up, we observed a low one-year TLR rate, and the rate of one-year MACE appeared very acceptable in this high-risk population. The prognosis of these patients is driven by the usual clinical and paraclinical parameters in CAD.

Impact on daily practice

Our data demonstrate that the RA procedure has a good clinical success rate and a low in-hospital complication rate in experienced centres. Multivariate analysis identified female gender, poor renal function, low left ventricular ejection fraction, ACS (with or without ST-elevation at admission) and the presence of unprotected left main stenosis as independent predictors of one-year MACE.

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Conflict of interest statement

F. Bouisset reports grants from Boston Scientific, during the conduct of the study, and personal fees from MSD, Abbott, Bayer, and Amgen, outside the submitted work. E. Barbato reports personal fees from Abbott Vascular and Boston Scientific, outside the submitted work. K. Reczuch reports personal fees from Boston Scientific, outside the submitted work. G. Cayla reports research grants and/or personal fees from Amgen, AstraZeneca, Abbott, Bayer, Boston Scientific, Biotronik, Bristol-Myers Squibb, Pfizer, and Sanofi-Aventis, outside the submitted work. T. Lhermusier reports personal fees and non-financial support from Boston Scientific, outside the submitted work. J. Palazuelos Molinero reports personal fees from Abbott, Boston Scientific, Biotronik,

EuroIntervention 2020;16:e305-e312

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Supplementary data

Supplementary Appendix 1. Definitions.

Supplementary Table 1. Participating centres, associated referring investigators, and country coordinators.

Supplementary Table 2. Rotational atherectomy procedural characteristics.

Supplementary Table 3. Medical therapy at discharge.

Supplementary Table 4. Multivariate analysis identifying independent predictors of in-hospital MACE.

Supplementary Table 5. Multivariate analysis identifying independent predictors of 30-day MACE.

Supplementary Table 6. Multivariate analysis determining independent predictors of one-year MACE.

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Supplementary data

Supplementary Appendix 1. Definitions

Acute myocardial infarction (MI)

The term acute myocardial infarction (MI) should be used when there is evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischaemia. Under these conditions, any of the following criteria meets the diagnosis for MI:

- Detection of a rise and/or fall of cardiac biomarker values (troponin, CPK, CK-MB) with at least one value above the 99th percentile upper normal limit (UNL) and with at least one of the following: • symptoms of ischaemia • new or presumed new significant ST-segment – T-wave (ST-T) changes or new left bundle branch block (LBBB) • development of pathological Q-waves in the ECG • imaging evidence of new loss of viable myocardium or new regional wall motion abnormality • identification of an intracoronary thrombus by angiography or autopsy.
- Cardiac death with symptoms suggestive of myocardial ischaemia and presumed new ischaemic ECG changes or new LBBB, but death occurred before cardiac biomarkers were obtained, or before cardiac biomarkers values would be increased.
- Percutaneous coronary intervention (PCI)-related MI is arbitrarily defined by elevation of troponin values (>5x99th percentile UNL) in patients with normal baseline values (≤99th percentile UNL) or a rise of troponin >20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial ischaemia, or (ii) new ischaemic ECG changes, or (iii) angiographic findings consistent with a procedural complication, or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required.
- Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischaemia and with a rise and/or fall of cardiac biomarker values in at least one value above the 99th percentile UNL.
- Coronary artery bypass grafting (CABG)-related MI is arbitrarily defined by elevation of cardiac biomarker values (>10x99th percentile UNL) in patients with normal baseline troponin values (≤99th percentile UNL). In addition, either (i) new pathological Q-waves or new LBBB, or (ii) angiographically documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

Angiographic success

Angiographic success is defined as a success of revascularisation of all treated lesions (residual stenosis <50%) and no per-procedure complications.

Bleeding

Bleeding events will be recorded as adverse events only if they are part of BARC 3, BARC 4 or BARC 5 (from BARC Bleeding definition).

Clinical success

Clinical success is defined as angiographic success and no complications within 24 hours post procedure.

Coronary revascularisation procedures

A coronary revascularisation procedure may be either a coronary artery bypass graft (CABG) surgery or a percutaneous coronary intervention (PCI). It may be classified as follows:

- Elective: an elective procedure is planned in advance and is not urgent or emergent.

- Emergent: an emergent procedure is performed as soon as possible after qualifying symptoms.
- Urgent: an urgent procedure is performed within 48 hours of qualifying symptoms.

Target lesion (TL): a lesion revascularised in the index procedure or in the staged procedure using the rotational atherectomy device.
Target vessel (TV): the main epicardial coronary artery or arteries (LMCA, LAD, LCX, or RCA) which contain the target lesion(s), including its branches, or grafts (arterial or venous) supplying the target lesion territory.
Target vessel – non-target lesion (TV–non-TL): the target vessel but non-target lesion consists of a lesion in the epicardial vessel/branch/graft that contains the target lesion; however, this lesion is outside of the target lesion by at least 5 mm distal or proximal to the target lesion determined by quantitative coronary angiography (QCA).
Non-target vessel (non-TV): the main epicardial coronary artery or arteries (LMCA, LAD, LCX, or RCA) which do not contain the target lesion(s), including its branches, or grafts (arterial or venous) supplying the target lesion territory.

Death
Death is divided into two categories.
Cardiovascular death is defined as death due to any of the following:
- Acute myocardial infarction.
- Cardiac perforation/pericardial tamponade.
- Arrhythmia or conduction abnormality.
- Stroke within 30 days of the procedure or stroke suspected of being related to the procedure.
- Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery.
- Any death in which a cardiac cause cannot be excluded.

Non-cardiac death is defined as a death not due to cardiac causes (as defined above).

Dissection
Percutaneous coronary intervention, which depends upon mechanical dilatation of the artery or ablation of atherosclerotic plaque, is requisitely associated with plaque fracture, intimal splitting and localised medial dissection — these tears may extend into the media for varying distances, and may even extend through the adventitia, resulting in frank perforation.

End of PCI procedure
The end of the procedure is the removal of the guidewire and the transfer of the subject from the laboratory of the catheterisation facility.

Index procedure
The index procedure is defined as the PCI procedure from crossing the target lesion with the guidewire until removal of the guiding catheter and the transfer of the subject from the laboratory of the catheterisation facility.

No reflow/slow flow
Defined as a sustained or transient reduction in antegrade flow that is not associated with an obstructive lesion at the treatment site.

Perforation

Coronary perforation occurs when a dissection or intimal tear propagates outward sufficient to penetrate the arterial wall completely.

Reintervention
Any repeat revascularisation of either a target vessel or a non-target vessel with any of the above, and which was not planned at the end of the index procedure will be considered as reintervention.

Target vessel revascularisation (TVR): target vessel revascularisation is any repeat PCI of the target vessel or bypass surgery of the target vessel.
Target lesion revascularisation (TLR): target lesion revascularisation is defined as any repeat PCI of the target lesion or CABG of the target vessel.

Resuscitation
Cardiac resuscitation is defined as an emergency procedure, often employed after cardiac arrest, in which cardiac massage, artificial respiration, and drugs are used to maintain the circulation of oxygenated blood to the brain.

Rotablation-related adverse event
Any adverse event for which a causal relationship between the device (Rotablator) or the related procedure and the event is at least a reasonable possibility.

Staged procedure
Staged procedures are defined as interventions planned at the time of the index procedure. If staged procedures are inevitable, the reason should be documented in the eCRF and source documents. The staged procedure should occur within three months post index procedure.

If a staged procedure occurs outside of the time window of three months after the baseline procedure, it will be recorded as a reintervention.

Stent thrombosis
Three categories of evidence are recognised in defining stent thrombosis.

1. Definite stent thrombosis is considered to have occurred by either angiographic or pathological confirmation:
    a. Angiographic confirmation*: the presence of an intracoronary thrombus that originates in the stent or in the segment 5 mm proximal or distal to the stent and presence of at least one of the following criteria within a 48-hour time window: acute onset of ischaemic symptoms at rest; new ischaemic ECG changes that suggest acute ischaemia; typical rise and fall in cardiac biomarkers (refer to definition of spontaneous MI: troponin or CK-MB >99th percentile of UNL); non-occlusive thrombus. Intracoronary thrombus is defined as a (spheric, ovoid, or irregular) non-calcified filling defect or lucency surrounded by contrast material (on three sides or within a coronary stenosis) seen in multiple projections, or persistence of contrast material within the lumen, or a visible embolisation of intraluminal material downstream - occlusive thrombus. TIMI 0 or TIMI 1 intrastent or proximal to a stent up to the most adjacent proximal side branch or main branch (if originating from the side branch).

b. Pathological confirmation: evidence of recent thrombus within the stent determined at autopsy or via examination of tissue retrieved following thrombectomy.

* The incidental angiographic documentation of stent occlusion in the absence of clinical signs or symptoms is not considered a confirmed stent thrombosis (silent occlusion).

2. Probable stent thrombosis is considered to have occurred after intracoronary stenting in the following cases:

- Any unexplained death within the first 30 days.
- Irrespective of the time after the index procedure, any myocardial infarction (MI) which is related to documented acute ischaemia in the territory of the target lesion without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause.

3. Possible stent thrombosis is considered to have occurred with any unexplained death from 30 days following intracoronary stenting until the end of trial follow-up.

Stroke

Defined as a cerebrovascular event (intracranial haemorrhage or non-haemorrhagic stroke) that meets the following four criteria:

1. Rapid onset of focal/global neurological deficit.
2. Duration ≥24 hrs or <24 hrs if:
    - Therapeutic intervention
    - Neuro-imaging
    - Death
3. No non-stroke cause (e.g., tumour, drug side effect, trauma, etc.).
4. Confirmation by at least one of:
    - a neurologist or neurosurgeon
    - neuro-imaging (CT, MRI or angio)
    - lumbar puncture (intracranial haemorrhage)
    - other compelling evidence of stroke.

Target lesion failure (TLF)

TLF is defined as the combination of cardiac death, target vessel myocardial infarction, or clinically ischaemia-driven target lesion revascularisation (TLR).

Supplementary Table 1. Participating centres, associated referring investigators and country coordinators.

1. France	0101	Toulouse	CHU Rangueil	Pr Didier Carrié (*)
	0103	Grenoble	La clinique des Eaux Claires	Dr Benjamin Faurie
	0104	Nantes	Les Nouvelles Cliniques Nantaises	Dr Erwan Bressollette
	0105	Nîmes	CHU de Nîmes	Pr Guillaume Cayla
2. Austria	0201	Graz	LKH Graz Süd-West	Dr Stefan Harb (*)
3. Germany	0402	Düsseldorf	Augusta Krankenhaus Düsseldorf	Dr Markus Meyer-Gessner (*)
4. Greece	0501	Thessalonica	St. Luke's Hospital	Dr Nicolaus Mezilis (*)
5. Italy	0701	Verona	Azienda Ospedaliera Universitaria Integrata di Verona	Pr Flavio Ribichini (*)
	0702	Udine	Azienda Sanitaria Universitaria Integrata di Udine	Dr Leonardo Spedicato
	0703	Perugia	Hospital Santa Maria della Misericordia di Perugia	Dr Rocco Sclafani
	0704	San Donato Milanese, Milan	IRCCS Policlinico San Donato	Dr Mauro Agnifili
6. Poland	0801	Wroclaw	4 Wojskowy Szpital Kliniczny z Poliklinika SPZOZ	Pr Krzysztof Reczuch (*)
	0802	Krakow	Interventional Cardiology Clinic, Jagiellonian University, John Paul II Hospital	Dr Wojciech Zajdel
	0803	Poznan	Department of Cardiology, Poznan University of Medical Sciences	Pr Maciej Lesiak
	0804	Bialystok	Department of Invasive Cardiology,	Pr Slawomir Dobrzycki

			Medical University of Bialystok	
7. Spain	1001	Madrid	Hospital Universitario Central de la Defensa Gómez Ulla	Dr Jorge Palazuelos Molinero (*)
	1002	Barcelona	Hospital del Mar	Dr Beatriz Vaquerizo
	1003	Murcia	Hospital Virgen de la Arrixaca	Pr Mariano Valdés
8. Russia	1401	Krasnoyarsk	Krasnoyarsk Regional Clinical Hospital - Regional Vascular Center	Dr Aleksey Protopopov (*)

Supplementary Table 2. Rotational atherectomy procedural characteristics.

RA procedure		N	(%)
Radial approach		692/964	71.8
Number of lesions treated with RA	1	725	75.0
	2	191	19.8
	≥3	50	5.2
Lesion treated with RA	Left main coronary artery	171/966	17.7
	Left descending artery	468/966	48.5
	Circumflex artery	149/966	15.4
	Right coronary artery	316/966	32.7
Calcified bifurcation lesion treated with RA		312/965	32.3
Chronic total occlusion treated with RA		78/964	8.1
Sheath diameter	5 Fr	15	1.6
	6 Fr	707	73.6
	7 or 7.5 Fr	196	20.4
	8 Fr	43	4.5
Mean number of burr runs for each lesion	<2	165	17.6
	2 or 3	406	43.2
	4	143	15.5
	≥5	226	24.0
Maximal burr diameter (mm)	1.25	266	27.6
	1.50	498	51.7
	≥1.75	199	20.7
Maximal burr speed (rpm)	<160,000	261	27.3
	160,000-180,000	535	55.9
	>180,000	161	16.8
Mean RA duration (sec) for each lesion	<30	253	27.5
	30–59	281	30.5
	≥60	386	42.0
Type of stent	DES	933	98.2
	BMS	10	1.1
	DES+BMS	5	0.5

	DES+BRS	2	0.2
Total number of stents		1.77	±0.9
Total stent length, mm*		47	±27
IVUS or OCT use		66	6.9

* Mean±SD.

BMS: bare metal stent; BRS: bioresorbable scaffold; DES: drug-eluting stent; RA: rotational atherectomy

Supplementary Table 3. Medical therapy at discharge.

Drugs		N	(%)
Aspirin		913/935	97.7
$P2Y_{12}$ inhibitor (any type)		924/935	98.8
	Clopidogrel	729/935	78.0
	Ticagrelor	213/935	22.8
	Prasugrel	23/935	2.5
Oral anticoagulation (any type)		188/935	20.1
	Vitamin K antagonist	64/935	6.8
	New oral anticoagulant	124/935	13.3
DAPT (aspirin+any $P2Y_{12}$ inhibitor)		903/935	96.6
TAT (aspirin+any $P2Y_{12}$ inhibitor+any oral anticoagulation)		175/935	18.7
Beta-blockers		764/935	81.7
Statin		827/935	88.5
ACE inhibitors		584/935	62.5
ARB		117/935	12.5

ACE: angiotensin-converting enzyme; ARB: angiotensin II receptor blockers; DAPT: dual antiplatelet therapy; TAT: triple antithrombotic therapy

Supplementary Table 4. Multivariate analysis identifying independent predictors of in-hospital MACE.

In-hospital MACE		Univariate			Multivariate		
		OR	**95% CI**	***p*-value**	**OR**	**95% CI**	***p*-value**
Patient characteristics							
Female gender		**1.87**	**1.01–3.47**	**0.047**			
Age, years *		1.01	0.99–1.04	0.333			
Diabetes mellitus		0.94	0.50–1.74	0.834			
Hypertension		1.16	0.51–2.65	0.721			
Dyslipidaemia		1.83	0.84–3.98	0.130			
Active tobacco use		0.95	0.41–2.20	0.907			
Obesity, BMI >30 kg/m²		0.74	0.34–1.63	0.459			
Previous stroke/TIA		0.87	0.34–2.26	0.777			
Previous MI		1.66	0.89–3.11	0.114			
Previous PCI		0.98	0.53–1.82	0.950			
Previous CABG		**0.27**	**0.07–1.14**	**0.075**	**0.21**	**0.05–0.91**	**0.037**
Killip class	I-II	**1.00**			**1.00**		
	III-IV	**6.32**	**2.20–18.14**	**0.001**	**4.86**	**1.47–16.10**	**0.010**
	Unknown	**1.14**	**0.56–2.33**	**0.714**	**1.37**	**0.64–2.92**	**0.415**
MDRD creatinine clearance, ml/min/1.73 m²	≥60	1.00					
	30-59	1.25	0.63–2.49	0.518			
	<30	1.43	0.48–4.24	0.516			

Haemoglobin, gr/dl *		0.99	0.86–1.13	0.838			
Clinical presentation is ACS (STEMI or NSTEMI)		**2.38**	**1.29–4.40**	**0.006**			
LVEF (%)	>35	1.00					
	≤35	1.85	0.76–4.52	0.179			
	Unknown	0.60	0.24–1.49	0.270			
Lesion characteristics							
Left main coronary artery stenosis		**2.64**	**1.43–4.88**	**0.002**	**2.66**	**1.38–5.12**	**0.003**
Number of diseased vessels	1	1.00					
	2	0.80	0.34–1.86	0.603			
	3	1.33	0.61–2.87	0.474			
Calcified bifurcation		1.57	0.86–2.89	0.142			
Chronic total occlusion		0.92	0.46–1.80	0.798			
Procedural characteristics							
Radial approach		1.56	0.74–3.28	0.245			
Number of lesions treated with RA	1	1.00					
	2	1.55	0.78–3.09	0.211			
	≥3	0.97	0.22–4.16	0.962			
Lesion treated with RA	Left main coronary artery	1.80	0.91–3.57	0.093			
	Left anterior descending artery	1.07	0.58–1.95	0.833			
	Circumflex artery	0.39	0.12–1.27	0.118			
	Right coronary artery	0.86	0.44–1.66	0.647			

Calcified bifurcation lesion treated with RA		1.21	0.64–2.26	0.559			
Chronic total occlusion treated with RA		0.25	0.03–1.87	0.179			
Sheath calibre	6 Fr	1.00					
	7 or 7.5 Fr	0.69	0.30–1.56	0.369			
	8 Fr	NC					
Total number of burr runs (for 1 or several lesions)	1	**1.00**			**1.00**		
	2	**1.53**	**0.28–8.49**	**0.626**	**1.73**	**0.31–9.79**	**0.537**
	≥3	**3.78**	**0.90–15.89**	**0.070**	**4.17**	**0.98–17.82**	**0.054**
Mean number of burr runs for each lesion	<2	1.00					
	2 or 3	1.87	0.62–5.60	0.265			
	4	2.70	0.81–8.97	0.104			
	≥5	2.06	0.64–6.59	0.223			
Maximal burr diameter, mm	1.25	1.00					
	1.50	0.75	0.37–1.52	0.427			
	≥1.75	0.95	0.41–2.19	0.909			
Maximal burr speed, rpm	<160,000	1.00					
	160,000–180,000	2.35	0.96–5.74	0.062			
	>180,000	2.52	0.88–7.21	0.086			
Mean RA duration for one lesion, sec	<30	1.00					
	30-59	1.32	0.55–3.13	0.536			
	≥60	1.48	0.66–3.31	0.338			

	Total RA duration, sec	<40	1.00					
		40-79	1.06	0.47–2.41	0.887			
		≥80	1.62	0.75–3.49	0.219			

BMI: body mass index; CABG: coronary artery bypass grafting; LVEF: left ventricular ejection fraction; MACE: major adverse cardiac events; MDRD: Modification of Diet in Renal Disease; MI: myocardial infarction; NSTEMI: non-ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; RA: rotational atherectomy; STEMI: ST-elevation myocardial infarction; TIA: transient ischaemic attack

Supplementary Table 5. Multivariate analysis identifying independent predictors of 30-day MACE.

30-day MACE		Univariate			Multivariate		
		HR	**95% CI**	***p*-value**	**HR**	**95% CI**	***p*-value**
Patient characteristics							
Female gender		**1.83**	**1.06–3.15**	**0.027**			
Age, years *		1.01	0.99-1.04	0.333			
Diabetes mellitus		1.08	0.63-1.86	0.769			
Hypertension		0.86	0.44-1.66	0.651			
Dyslipidaemia		1.14	0.62-2.10	0.668			
Active tobacco use		1.00	0.48-2.06	0.994			
Obesity, BMI >30 kg/m²		0.67	0.33–1.38	0.277			
Peripheral vascular disease		1.32	0.73–2.39	0.362			
Previous stroke/TIA		1.18	0.55-2.50	0.674			
Previous MI		1.28	0.73-2.27	0.390			
Previous PCI		0.76	0.43-1.34	0.342			
Previous CABG		0.34	0.11-1.10	0.073			
Killip class	I-II	**1.00**	**(ref)**		**1.00**	**(ref)**	
	III-IV	**4.20**	**1.65-10.69**	**0.003**	**2.99**	**1.05-8.56**	**0.041**
	Unknown	**0.94**	**0.49-1.80**	**0.845**	**1.09**	**0.55-2.16**	**0.803**
MDRD creatinine clearance, ml/min/1.73 m²	≥60	**1.00**	**(ref)**				
	30-59	**1.16**	**0.62-2.14**	**0.644**			
	<30	**1.43**	**0.56-3.68**	**0.457**			

Haemoglobin, gr/dl *		0.99	0.86-1.13	0.838			
Clinical presentation is ACS (STEMI or NSTEMI)		**2.44**	**1.43-4.17**	**0.001**	**2.12**	**1.20-3.75**	**0.010**
LVEF (%)	>35	**1.00**	**(ref)**				
	≤35	**1.39**	**0.71–2.72**	**0.330**			
	Unknown	**0.42**	**0.13–1.34**	**0.143**			
Lesion characteristics							
Left main coronary artery stenosis		**2.27**	**1.33-3.90**	**0.003**			
Number of diseased vessels	1	1.00	(ref)				
	2	1.31	0.59-2.89	0.507			
	3	1.80	0.84-3.84	0.129			
Calcified bifurcation		1.47	0.86-2.51	0.159			
Chronic total occlusion		0.94	0.52-1.71	0.842			
Procedural characteristics							
Radial approach		1.25	0.67-2.33	0.483			
Number of lesions treated with RA	1	1.00	(ref)				
	2	1.17	0.61-2.23	0.641			
	≥3	1.11	0.34-3.58	0.865			
Lesion treated with RA	Left main coronary artery	1.64	0.89-3.02	0.111			
	Left anterior descending artery	1.24	0.73-2.12	0.427			
	Circumflex artery	0.68	0.29-1.60	0.379			
	Right coronary artery	0.71	0.39-1.31	0.271			

Calcified bifurcation lesion treated with RA		1.23	0.71-2.14	0.455			
Chronic total occlusion treated with RA		0.43	0.10-1.77	0.241			
Sheath calibre	6 Fr	1.00	(ref)				
	7 or 7.5 Fr	0.85	0.43-1.69	0.643			
	8 Fr	0.39	0.05-2.80	0.346			
Total number of burr runs (for 1 or several lesions)	1	**1.00**	**(ref)**		**1.00**	**(ref)**	
	2	**2.30**	**0.46-11.38**	**0.309**	**2.21**	**0.44-11.07**	**0.333**
	≥3	**4.51**	**1.09-18.61**	**0.037**	**4.27**	**1.03-17.71**	**0.046**
Mean number of burr runs for each lesion	<2	1.00	(ref)				
	2 or 3	2.16	0.74-6.29	0.159			
	4	3.52	1.13-10.90	0.029			
	≥5	2.78	0.92-8.37	0.069			
Maximal burr diameter, mm	1.25	1.00	(ref)				
	1.50	0.67	0.37-1.22	0.188			
	≥1.75	0.77	0.36-1.61	0.481			
Maximal burr speed, rpm	<160,000	**1.00**	**(ref)**				
	160,000–180,000	**1.96**	**0.90-4.26**	**0.088**			
	>180,000	**2.68**	**1.11-6.47**	**0.028**			
Mean RA duration for one lesion, sec	<30	1.00	(ref)				
	30-59	1.40	0.66-2.99	0.385			
	≥60	1.44	0.70-2.94	0.318			

	Total RA duration, sec	<40	1.00	(ref)				
		40-79	1.15	0.57-2.32	0.692			
		≥80	1.39	0.70-2.74	0.350			

BMI: body mass index; CABG: coronary artery bypass grafting; LVEF: left ventricular ejection fraction; MACE: major adverse cardiac events; MDRD: Modification of Diet in Renal Disease; MI: myocardial infarction; NSTEMI: non-ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; RA: rotational atherectomy; STEMI: ST-elevation myocardial infarction; TIA: transient ischaemic attack

Supplementary Table 6. Multivariate analysis determining independent predictors of one-year MACE.

One-year MACE		Univariate			Multivariate		
		HR	**95% CI**	***p*-value**	**HR**	**95% CI**	***p*-value**
Patient characteristics							
Female gender		**1.71**	**1.20-2.45**	**0.003**	**1.70**	**1.18-2.47**	**0.005**
Age, years *		1.01	0.99-1.03	0.431			
Diabetes mellitus		1.31	0.92-1.86	0.129			
Hypertension		0.82	0.54-1.25	0.361			
Dyslipidaemia		0.91	0.62-1.33	0.622			
Active tobacco use		1.00	0.62-1.61	0.998			
Obesity, BMI >30 kg/m²		**0.55**	**0.33-0.91**	**0.019**			
Peripheral vascular disease		1.08	0.72-1.62	0.716			
Previous stroke/TIA		1.47	0.94-2.32	0.093			
Previous MI		1.24	0.86-1.80	0.256			
Previous PCI		1.00	0.70-1.42	0.980			
Previous CABG		0.77	0.45-1.31	0.333			
MDRD creatinine clearance, ml/min/1.73 m²	≥60	**1.00**	**(ref)**		**1.00**	**(ref)**	
	30-59	**1.47**	**0.99-2.17**	**0.050**	**1.24**	**0.84-1.84**	**0.284**
	<30	**2.08**	**1.19-3.65**	**0.010**	**1.77**	**1.01-3.12**	**0.048**
Haemoglobin, gr/dl *		**0.92**	**0.85-0.99**	**0.028**			
Clinical presentation is STEMI or NSTEMI		**1.89**	**1.32-2.71**	**<0.001**	**1.59**	**1.09-2.31**	**0.016**
LVEF, %	≥35	**1.00**	**(ref)**		**1.00**	**(ref)**	

		<35	**1.71**	**1.11-2.63**	**0.016**	**1.61**	**1.02-2.55**	**0.040**
		Unknown	**1.05**	**0.62-1.80**	**0.852**	**1.09**	**0.64-1.86**	**0.754**
Lesion characteristics								
	Left main coronary artery stenosis		**1.89**	**1.32-2.71**	**<0.001**	**1.62**	**1.12-2.35**	**0.011**
	Number of diseased vessels	1	**1.00**	**(ref)**				
		2	**1.27**	**0.74-2.15**	**0.387**			
		3	**1.98**	**1.20-3.27**	**0.007**			
	Calcified bifurcation		1.10	0.77-1.57	0.611			
	Chronic total occlusion		1.11	0.76-1.62	0.579			
Procedural characteristics								
	Radial approach		1.44	0.94-2.20	0.093			
	Number of lesions treated with RA	1	1.00	(ref)				
		2	1.13	0.74-1.73	0.575			
		≥3	1.07	0.49-2.30	0.871			
	Lesion treated with RA	Left main coronary artery	1.25	0.82-1.91	0.301			
		Left anterior descending artery	1.03	0.73-1.46	0.865			
		Circumflex artery	1.08	0.68-1.72	0.750			
		Right coronary artery	0.89	0.61-1.30	0.559			
	Calcified bifurcation lesion treated with RA		0.85	0.58-1.24	0.399			
	Chronic total occlusion treated with RA		0.75	0.37-1.53	0.429			
	Sheath calibre	6 Fr	1.00	(ref)				

		7 or 7.5 Fr	0.68	0.42-1.10	0.120			
		8 Fr	0.15	0.02-1.08	0.060			
	Total number of burr runs (for 1 or several lesions)	1	**1.00**	**(ref)**				
		2	**1.99**	**0.96-4.15**	**0.066**			
		≥3	**1.93**	**1.01-3.71**	**0.049**			
	Mean number of burr runs for each lesion	<2	1.00	(ref)				
		2 or 3	1.83	1.04-3.22	0.035			
		4	1.37	0.68-2.74	0.376			
		≥5	1.50	0.80-2.80	0.201			
	Maximal burr diameter, mm	1.25	1.00	(ref)				
		1.50	1.03	0.69-1.55	0.871			
		≥1.75	0.80	0.47-1.37	0.418			
	Maximal burr speed, rpm	<160,000	1.00	(ref)				
		160,000-180,000	1.26	0.82-1.94	0.295			
		>180,000	1.19	0.68-2.09	0.534			
	Mean RA duration for one lesion, sec	<30	1.00	(ref)				
		30-59	1.24	0.78-1.97	0.365			
		≥60	1.00	0.64-1.58	0.986			
	Total RA duration, sec	<40	1.00	(ref)				
		40-79	0.91	0.59-1.41	0.682			
		≥80	0.99	0.64-1.53	0.951			

BMI: body mass index; CABG: coronary artery bypass grafting; LVEF: left ventricular ejection fraction; MACE: major adverse cardiac events; MDRD: Modification of Diet in Renal Disease; MI: myocardial infarction; NSTEMI: non-ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; RA: rotational atherectomy; STEMI: ST-elevation myocardial infarction; TIA: transient ischaemic attack