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

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Short title: Prognostic factors in coronary angioplasty with rotational atherectomy

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First author portrait

(2) **Abstract**

Aims:

Despite the use of rotational atherectomy (RA) in interventional cardiology for over three decades, data regarding factors affecting the clinical outcomes of RA procedure remain scarce.

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 yo, 72.4% were male and 43.4% had diabetes. Initial presentation was an acute coronary syndrome (ACS) for 25.1% of 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 1 year, the rate of MACE was 13.2%. Factors independently associated with the occurrence of MACE at 1 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 mid-term results.

(3) **Classifications**:

Atherectomy

Rotablator

Multiple vessel disease

Calcified stenosis

Left Main

Undilatable lesion

(4) **Condensed abstract**

This paper presents the Euro 4C registry, the first large international prospective cohort focusing on percutaneous coronary intervention procedure performed with rotational atherectomy. This study included 966 patients from 19 centres and 8 European countries. The medical condition of these patients was very severe : 43.4% had diabetes, 25% had a left main lesion, 38.1% had three-vessel disease, and 29% had at least one chronic total occlusion. Despite the high level of complexity of this population, rotablation technique provided good immediate and mid-term results with 91.9% of clinical success and a rate of MACE of 13.2% at 1-year follow-up.

(5) **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 Event

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

(6) **Introduction**

With the expansion of percutaneous coronary intervention (PCI) indications towards 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 candidate 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. Indeed, 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 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.

(7) **Methods**

Study design and population

The Euro4C registry is a prospective, observational and multicentric European registry conducted in 19 centres, based in 8 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 at 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 to the study. Follow-up was performed by phone call at day 30 and at 1 year.

Data collection

Data at baseline and during follow-up were collected through an e-CRF. Initial clinical presentation and angiographic data describing the topography and the extension of the coronary disease were recorded.

Rotational atherectomy procedure

RA procedures were performed using the Boston Scientific Rotablator® system. Characteristics of the RA procedure were extensively recorded. According to the

definition of the European bifurcation club consensus(9), a lesion was considered as 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 exclusively treated with drug eluting stents (DES) in 98.2% of cases.

Outcomes

The primary endpoint was a composite endpoint defined as the cumulative incidence of cardiovascular death, myocardial infarction, target lesion revascularisation (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 peri-procedural complications) and the incidence of in-hospital complications including coronary perforation, coronary dissection, coronary low flow or no-flow, emergency CABG, tamponade, myocardial infarction (MI), stroke or transient ischemic attack (TIA), bleeding events (according to the BARC classification(10)) and death. Detailed definitions of these end-points are presented in the appendix.

Statistical analysis

Statistical analysis was performed on STATA statistical software, release 14.1 (Stata Corporation, College Station, Texas, USA). Continuous variables were summarized as means and standard deviations for normal distributions, and as medians and

interquartile ranges when distributions were not normally distributed. Categorical variables are presented as proportions.

In order to identify factors associated with the occurrence of the primary and secondary endpoint, differences between groups were tested using 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 Cox model.

(8)Results

Between October 2016 and July 2018, 1016 consecutive patients were included in the study. Distribution of patients according to their country of inclusion is shown in **Supplementary Table 1**. Fifty patients were excluded because of missing data, 966 patients were thus 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 patients characteristics

Mean age was 74.5 yo and 72.4% were male. The presentation was stable for 64.1% of patients, 4.2% presented with STEMI, 20.9% with 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 on the LMCA (*i.e.* ≥ 50%), 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. Intra-coronary 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**.

In-hospital outcomes

The rate of clinical success, defined as an angiographic success and no post-procedure complications within 24h, was 91.9%. In-hospital MACE occurred in 45 patients (4.7%). Rates of death and post-procedure myocardial infarction were 1.6% and 2.9%, respectively. Coronary perforation occurred in 16 patients (1.7% of cases) leading to a cardiac tamponade in 5 patients (0.5%). No cases of emergency CABG were recorded.

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 ≥ 7 Fr group, p= 1.00). In-hospital outcomes are summarised in **Table 3**.

Medical therapy at discharge

Nine hundred and three patients (96.6%) had a dual anti platelet therapy (DAPT) at discharge and 188 (20.1%) had an oral anticoagulant therapy. Betablockers 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 by cardiovascular death, MI, stroke or TIA, TLR or CABG was 5.6% and 13.2% at 30 days and 1 year, respectively. The rate of all-cause death was 2.5% at 30-day (2.1% for cardiovascular death) and 9.7% at one year (5.7% for cardiovascular death) The 30-day and 1-year outcomes are detailed in **Table 4**.

Predictors of MACE

Multivariate analysis identified Killip class 3/4 [OR= 4.86 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 3/4 [OR= 2.99 CI(1.05 – 8.56) p=0.041] , 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)**.

At 1-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], 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 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** and **Supplementary Table 6)**.

(9) 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 of 4.9% of in-hospital MACE.

2/ The rate of 1-year 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 1-year MACE are common clinical factors in CAD, *e.g.* renal failure, ACS at admission, low LVEF, and LMCA stenosis. Interestingly, female gender was also independently associated with worse mid-term 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 available largest registry conducted on RA to date, the retrospective ROTATE registry, performed between 2002 and 2013, in which the femoral approach was performed 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 in our registry. This preferential utilisation of smalls burrs is in line with the concept of plaque modification described previously. Although the access site

was not independently related to short and mid-term MACE in our cohort, it is well-known that radial approach allows to reduce access-site related complications in PCI(12, 13).

Low flow and no flow rate was relatively low in our cohort (1.2%). As centres participating to the study are very familiar with RA, this probably reflects that the procedures were done 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 intra coronary nitrates between runs.

A certain degree of disparity among countries regarding the technical approach of RA was observed, although these were not independently related to mid-term outcomes. Similarly, such technical parameters were not identified as independent predictors of MACE in previous studies either(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 (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 greater MACE rate.

The 1-year MACE rate observed in this registry was 13.2%, and is mainly related to cardiovascular death (5.7%) and MI (4.7%). In a recent meta-analysis that pooled 18441 subjects included in 18 trials treated by PCI with DES, Kedhi *et al* reported 1-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.

Indeed, 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 result, at least partially, to a largest use of second generation DES (98.2% vs 69.3% in ROTATE). Indeed, 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 an excellent 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 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 report 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 females 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, toward 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.

Acute coronary syndrome as 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 assessed the use of RA in the context of ACS(21, 22). They demonstrated that RA is feasible in this setting with similar safety outcomes than in the context of stable CAD, but worse

outcomes at mid-term follow-up. Renal failure was also identified as an independent predictor of 1-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 was confirmed since then, despite the critical advances achieved in the management of this pathology.

(10) Limitations

The main limitation of this study is the observational design. Indeed, the decision of using RA was left at each centre discretion and no central corelab analysed the procedures for endpoint definition. Thus, no pre and post procedural systematic QCA analysis were performed. Data regarding the global complexity of the coronary anatomy or on the level of risk of the patients in our population were not available.

(11) Conclusion

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 high clinical success rate. During follow-up, we observe a low one-year TLR, 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.

(12) Impact on daily practice

Our data demonstrate that 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 presence of unprotected left main stenosis as independent predictors of 1-year MACE.

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(16) Figure legends

Figure 1 : Distribution of enrolled subject according to the country of inclusion

Figure 2 : Independent predictors for mid-term major adverse cardiovascular events

(17) Tables

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		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 +/- DS

Table 1: Baseline clinical characteristics of the population

BMI: Body Mass Index; TIA: Transient Ischemic Attack; MI: Myocardial Infarction; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Grafting; MDRD: Modification of Diet in Renal Disease ; STEMI: ST Elevation Myocardial Infarction; NSTEMI: Non-ST Elevation Myocardial Infarction; LVEF: Left Ventricular Ejection Fraction; SD: Standard Deviation

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

Table 2: Baseline angiographic characteristics of the population

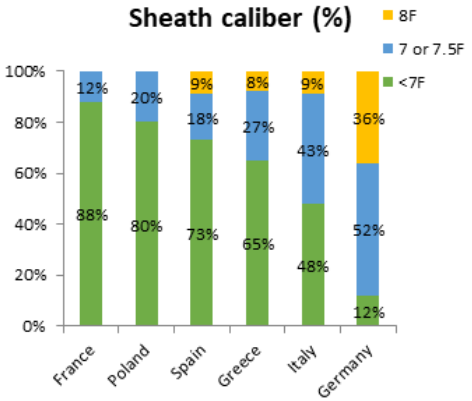
In-hospital outcomes	N	(%)
Clinical success	885/963	91.9
MACE	**45/966**	**4.7**
Death	15/965	1.6
Myocardial Infarction	**28/965**	**2.7**
Stroke or TIA	3/965	0.3
Perforation	16/965	1.7
Dissection	38/965	3.9
Low flow / no flow	12/965	1.2
Emergency CABG	0/965	0.0
Tamponade	5/965	0.5
Bleeding (BARC ≥ 3)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

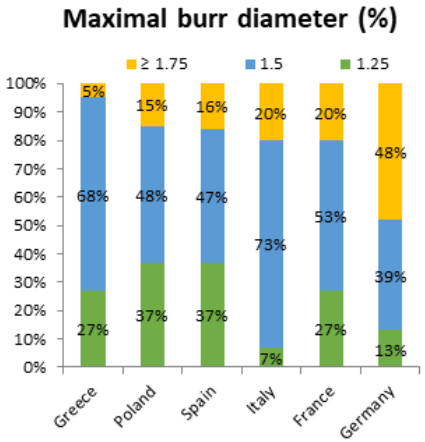
Table 3: In-hospital outcomes
TIA: Transient Ischemic Attack; CABG: Coronary Artery Bypass Grafting

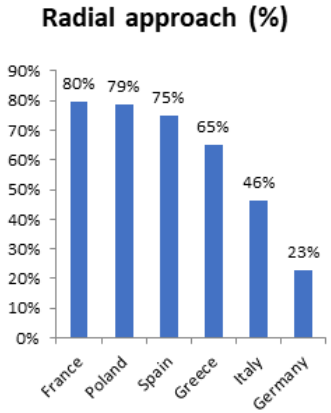
Outcomes	30-day outcomes		1-year outcomes		
	N	(%)	N	(%)	Incidence rate (for 100 person-year) **
MACE *	54/966	5.6	127/966	13.2	15.9 (13.4 - 18.9)
All-cause death	24/966	2.5	94/966	9.7	11.1 (9.1 - 13.6)
Cardiovascular death	20/966	2.1	55/966	5.7	6.5 (5.0 - 8.5)
Myocardial infarction	28/966	2.9	45/966	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)

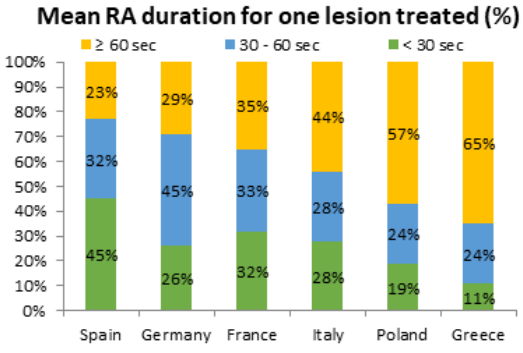
* Cardiovascular death, MI, Stroke/TIA, TLR or CABG; ** 95% confidence interval; ***: TLR or TVR;
MACE: Major Adverse Cardiac Event

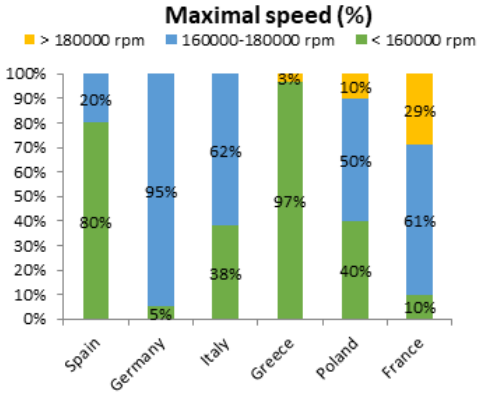
Table 4: 30-day and 1-year outcome

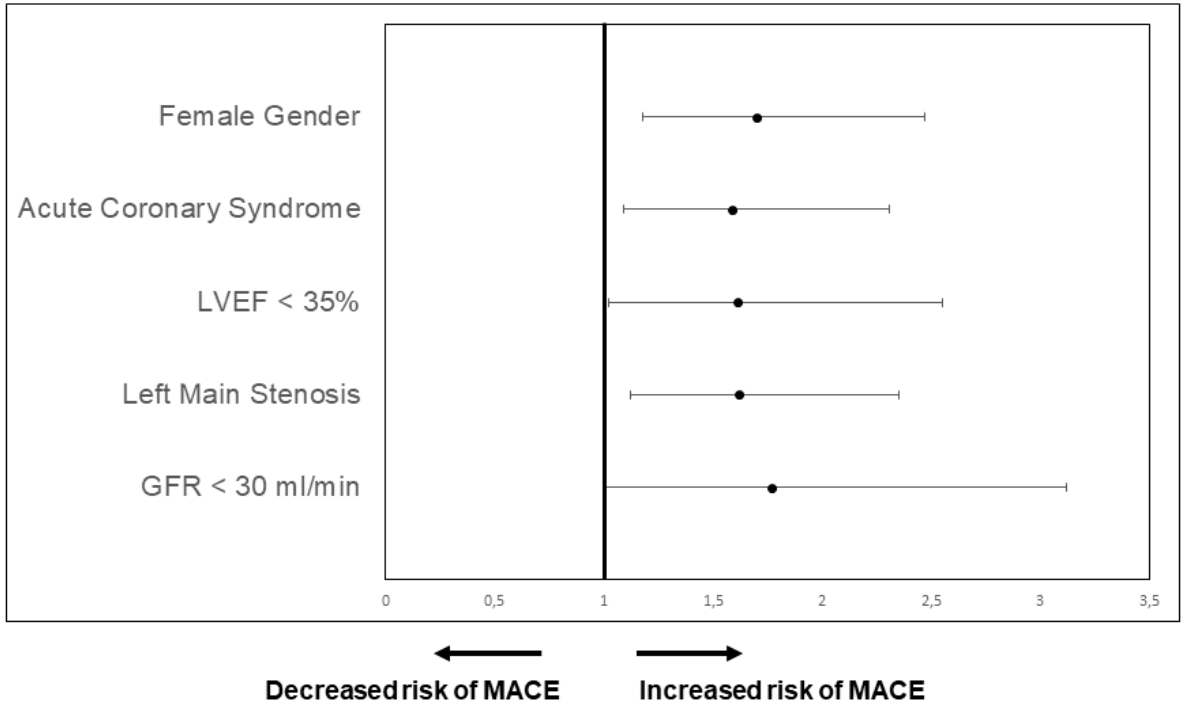












(20) Supplementary materials

1/ Participating centers, 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 Polikliniką SPZOZ	Pr Krzysztof Reczuch (*)
	0802	Krakow	Interventional Cardiology	Dr Wojciech Zajdel

			Clinic, Jagiellonian University, John Paul II Hospital	
	0803	Poznan	Department of Cardiology, Poznan University of Medical Sciences	Pr Maciej Lesiak
	0804	Bialystok	Department of Invasive Cardiology, Medical University of Bialystok	Pr Slawomir Dobrzycki
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 1: Participating centers, associated referring investigators, and country coordinator

2/ 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 ischemia. 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 99th percentile upper normal limit (UNL) and with at least one of the following: • Symptoms of ischemia • 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 ischemia and presumed new ischemic 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 (> 5 x 99th 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 ischemia or (ii) new ischemic 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 ischemia 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 (>10 x 99th 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) angiographic 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

The 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 event only if they are part of BARC 3, BARC 4 or BARC 5 (from BARC Bleeding definition table below).

CLINICAL SUCCESS

A clinical success is defined as an angiographic success and no complications within 24h 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 48h 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 – nonTL): 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 determines 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 2 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

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

INDEX PROCEDURE

The Index procedure is defined as 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 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 completely penetrate the arterial wall.

REINTERVENTION

Will be considered as reintervention any repeat revascularisation of either a target vessel or nontarget vessel with any of the above, and which was not planned at the end of the index procedure.

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 3 months post index procedure.

If a staged procedure occurs outside of the time window of 3 months after the baseline procedure, it will be recorded as a reintervention.

STENT THROMBOSIS

Three categories of evidence are recognized 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 1 of the following criteria within a 48h time window: - Acute onset of ischemic symptoms at rest - New ischemic ECG changes that suggest acute ischemia - 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) noncalcified filling defect or lucency surrounded by contrast material (on 3 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 originates 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 ischemia 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 end of trial follow up.

STROKE

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

1. Rapid onset of focal/global neurological deficit
2. Duration ≥ 24h or < 24h if:
    - Therapeutic intervention
    - Neuro-imaging
    - Death

3. No non-stroke cause (e.g. tumor, 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)

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

3/ Supplementary tables

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 Descendant 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 +/- DS

Supplementary table 2: Rotational atherectomy procedural characteristics
RA: Rotational Atherectomy; DES: Drug Eluting Stent; BMS: Bare Metal Stent; BRS: Bioresorbable Scaffold

Drugs		N	(%)
Aspirin		913/935	97.7
P2Y12 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 P2Y12 inhibitor)		903/935	96.6
TAT (Aspirin + any P2Y12 inhibitor + any Oral anticoagulation)		175/935	18.7
Betablockers		764/935	81.7
Statin		827/935	88.5
ACE inhibitors		584/935	62.5
ARB		117/935	12.5

Supplementary table 3: Medical therapy at discharge
DAPT: Dual Anti-Platelets Therapy; TAT: Triple Anti-Thrombotic Therapy; ACE: Angiotensin Converting Enzyme; ARB: Angiotensin II Receptors Blockers.

In hospital MACE		Univariate			Multivariate		
		OR	95% CI	p value	OR	95% CI	p value
Patients 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		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			
Lesions 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 descendant 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			

Supplementary table 4: Multivariate analysis identifying independent predictors of in-hospital MACE
MACE : Major Adverse Cardiac Event; BMI: Body Mass Index; TIA: Transient Ischaemic Attack; MI : Myocardial Infarction; PCI : Percutaneous Coronary Intervention; CABG : Coronary Artery Bypass Grafting; MDRD: Modification of Diet in Renal Disease; STEMI: ST Elevation Myocardial Infarction; NSTEMI: Non-ST Elevation Myocardial Infarction; LVEF: Left Ventricular Ejection Fraction; RA : Rotational Atherectomy

30-day MACE		Univariate			Multivariate		
		HR	95% CI	p value	HR	95% CI	p value
Patients 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		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**			
Lesions 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 descendant 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			

Supplementary table 5: Multivariate analysis identifying independent predictors of 30-day MACE

MACE: Major Adverse Cardiac Event; BMI: Body Mass Index; TIA: Transient Ischaemic Attack; MI : Myocardial Infarction; PCI : Percutaneous Coronary Intervention; CABG : Coronary Artery Bypass Grafting; MDRD: Modification of Diet in Renal Disease; STEMI: ST Elevation Myocardial Infarction; NSTEMI: Non-ST Elevation Myocardial Infarction; LVEF: Left Ventricular Ejection Fraction; RA : Rotational Atherectomy

One-year MACE		Univariate			Multivariate		
		HR	95% CI	p value	HR	95% CI	p value
Patient's 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		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**
Lesions 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 descendant 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			

Supplementary table 6: Multivariate analysis determining independent predictors of 1-year MACE

MACE: Major Adverse Cardiac Event; BMI: Body Mass Index; TIA: Transient Ischaemic Attack; MI: Myocardial Infarction; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Grafting; MDRD: Modification of Diet in Renal Disease; STEMI: ST Elevation Myocardial Infarction; NSTEMI: Non-ST Elevation Myocardial Infarction; LVEF: Left Ventricular Ejection Fraction; RA: Rotational Atherectomy