2019 euro PCR

EuRo4C registry

Results of the prospective European Registry on Rotational Atherectomy

Didier Carrié MD, Krzysztof Reczuch MD, Konrad Dobrzycki MD,Markus Meyer-Gessner MD, Erwan Bressollette MD,Guillaume Cayla MD, Kw Zajdel MD,M Mezilis MD,Benjamin Faurie MD,Maciej Lesiak MD,M Valdes MD,Jorge Palazuelos MD,Beatriz Vaqueiro MD,A Protopopov MD,Flavio Ribichini MD…

On behalf of EURO4C Registry investigators

23 May 2019

Speaker's name : Didier Carrié

☑ I do not have any potential conflict of interest to declare

Boston Scientific provided a grant for data monitoring

Background and Objectives

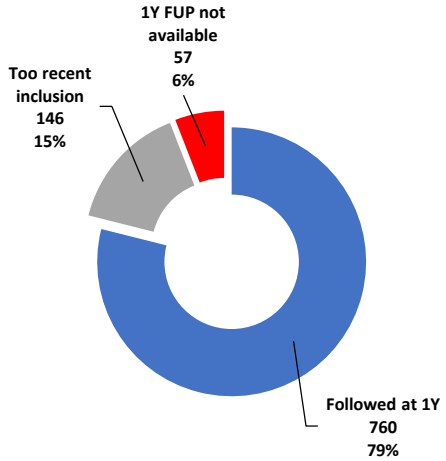
- Safety and efficacy of Rotational Atherectomy **(RA)** is largely unknown
- European data in the literature are very scarce
- To observe the **differences of practice in European countries**
- To identify factors associated with clinical outcomes :

  - **Primary outcome**
    - Composite safety endpoint: cumulative occurrence of cardiovascular death, myocardial infarction, target lesion revascularization, stroke, and coronary bypass **(MACE at 1 year)**

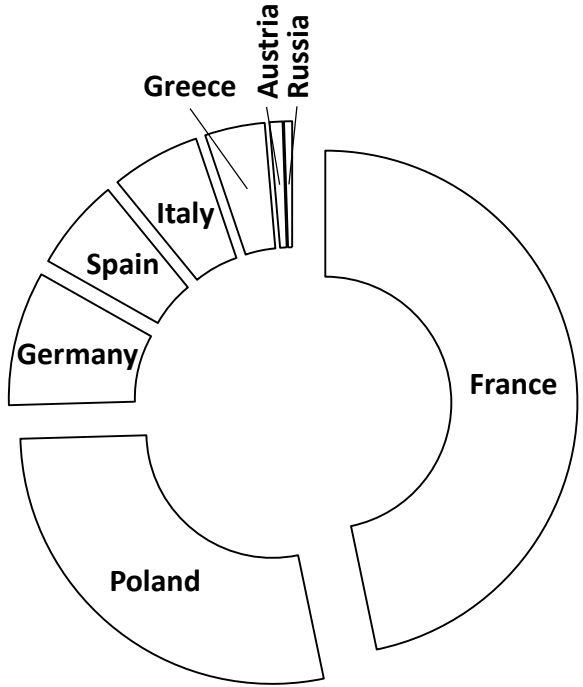
  - **Secondary outcomes**
    - Clinical success (success of revascularisation + no peri-procedural complication)
    - Frequency of in-hospital adverse events

Methods

- 19 participating centers in 8 participating countries : France, Poland, Germany, Spain, Italy, Greece, Austria and Russia
- Standardized data collection (eCRF)
- 1016 consecutive patients included (October 2016 to July 2018)
  - 53 not retained for analysis because of missing data for RA procedure
- 963 patients retained for data analysis



Distribution by country
(n=963)



Results

Baseline clinical data	N	%
Male gender	697/963	72.4
Age (years) *	74.5	+/- 9.8
Diabetes Mellitus	415/953	43.6
Peripheral vascular disease	219/892	24.6
MDRD creatinine clearance (ml/min/1,73 m²)		
< 30	70	7.4
30-59	258	27.4
≥ 60	613	65.1
Clinical presentation		
STEMI	40	4.2
NSTEMI	202	21.0
Unstable angina	104	10.8
Stable angina or silent ischaemia	616	64.0

* Mean +/- standard deviation.

Results

Baseline angiographic data	N	%
Unprotected LM	241/963	25.0
Severely impaired LV function (≤ 35%)	139/838	16.6
Coronary extension		
1 vessel	226	23.5
2 vessels	369	38.3
3 vessels	368	38.2
Severely calcified bifurcation	359/962	37.3
Chronic total occlusion	280/963	29.1

Results

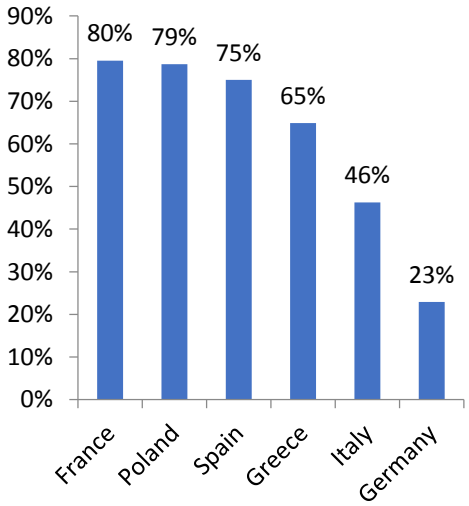
RA procedure(s)	N	%
Radial approach for index procedure	691/961	71.9
Total number of lesions treated with RA 1 2 ≥ 3	 722 191 50	 75.0 19.8 5.2
LM treated with RA	171/963	17.8
LAD treated with RA	467/963	48.5
Circumflex treated with RA	149/963	15.5
RCA treated with RA	314/963	32.6
Severely calcified bifurcation treated with RA	312/962	32.4
Chronic total occlusion treated with RA	78/961	8.1

Results

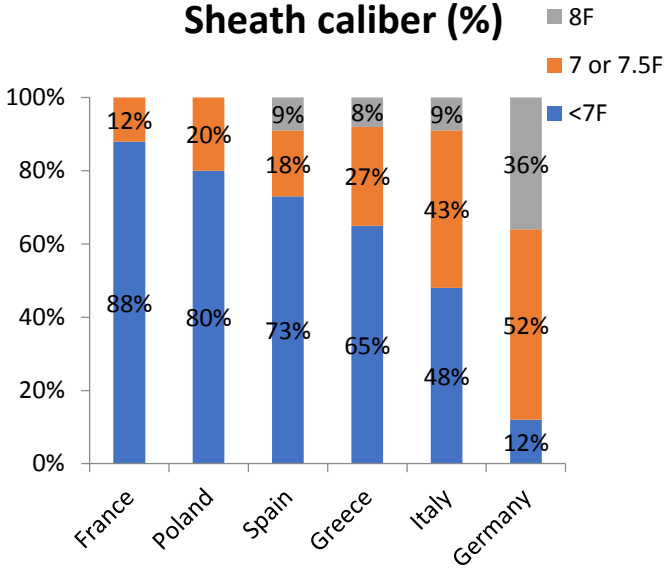
RA procedure(s)	N	%
Mean number of burr runs *(for 1 lesion treated)*		
<2	163	17.4
2 – 3	405	43.2
4	143	15.3
≥ 5	226	24.1
Maximal burr diameter used (mm)		
1.25	266	27.7
1.50	496	51.7
≥ 1.75	198	20.6
Maximal speed (rpm)		
< 160.000	261	27.4
160.000 – 180.000	532	55.7
> 180.000	161	16.9
Mean RA duration (sec) *(for 1 lesion treated)*		
< 30	250	27.3
30 – 60	281	30.6
≥ 60	386	42.1

Procedural characteristics of RA according to country

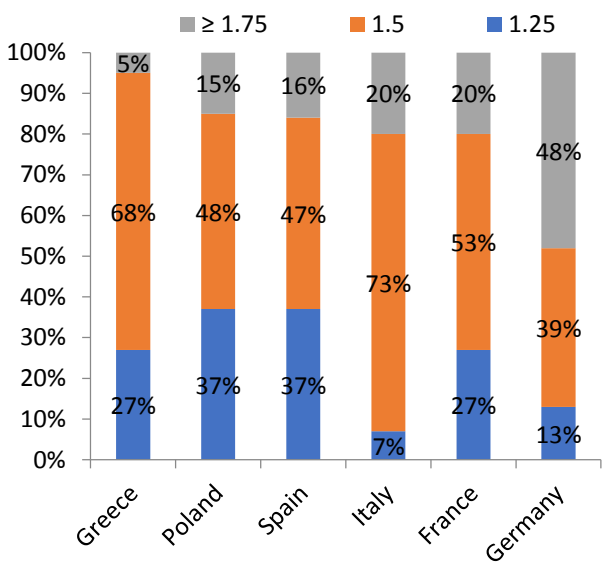
Radial approach (%)



Sheath caliber (%)

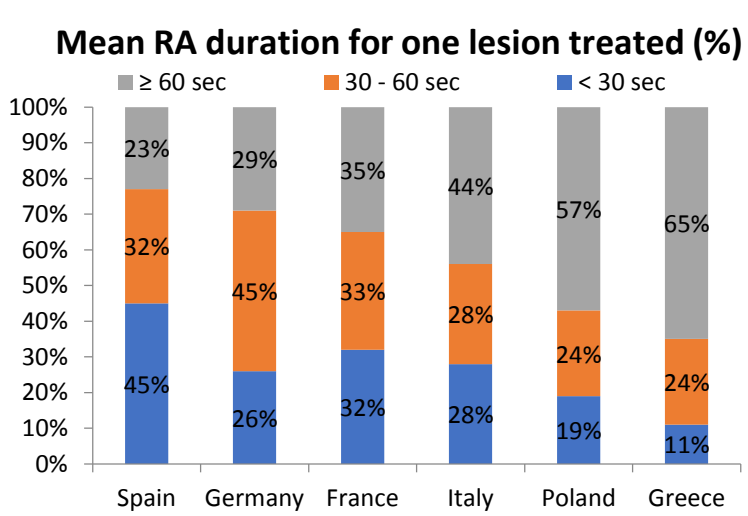


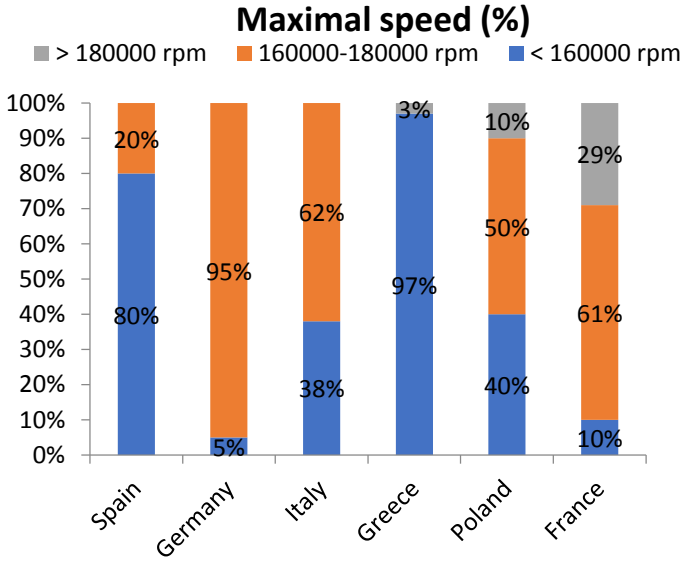
Maximal burr diameter (%)



(for countries with > 30 RA procedures available.

Procedural characteristics of RA according to country





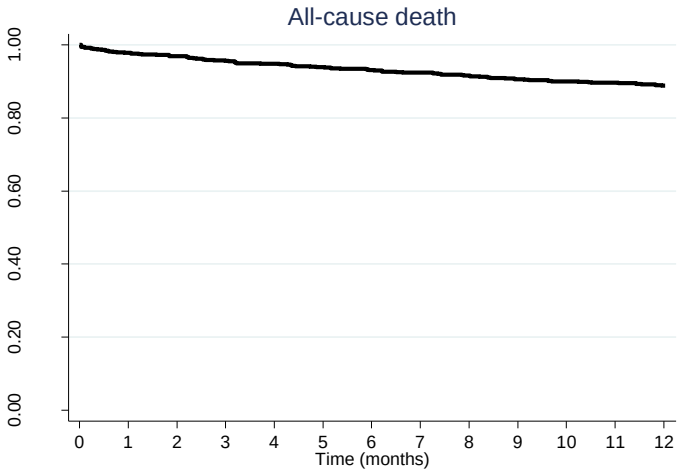
(for countries with > 30 RA procedures available.

In-hospital Results

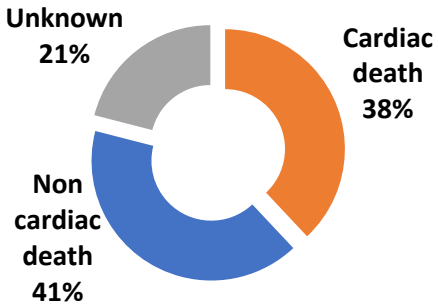
- **Clinical success** *(success of revascularisation + no per-proc. complication)* **: 91.9%**

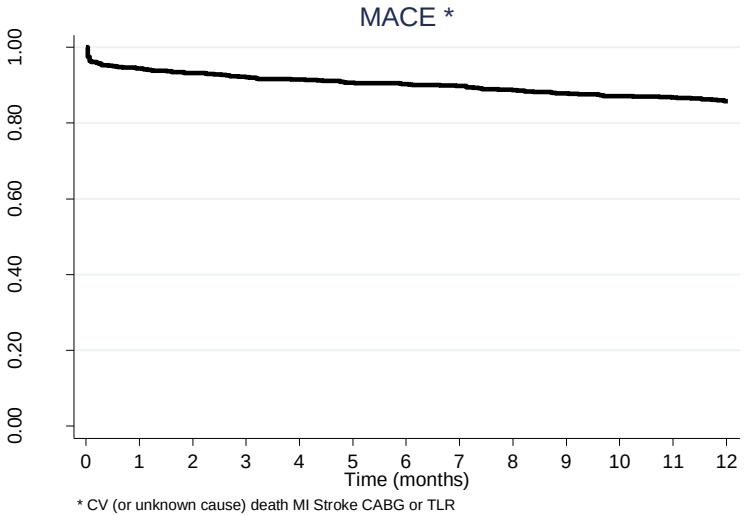
In-hospital complications	N	%
Perforation	16/962	1.7
Dissection	38/962	4.0
Low flow / no flow	12/962	1.3
Emergency CABG	0/962	0.0
Tamponnade	1/962	0.1
MI	30/962	3.1
Stroke / TIA	3/962	0.3
Death	15/962	1.6

Global Mortality and MACE rate at 1-Year clinical Follow-up



- Mortality rate : **12.5** for 100 persons / year



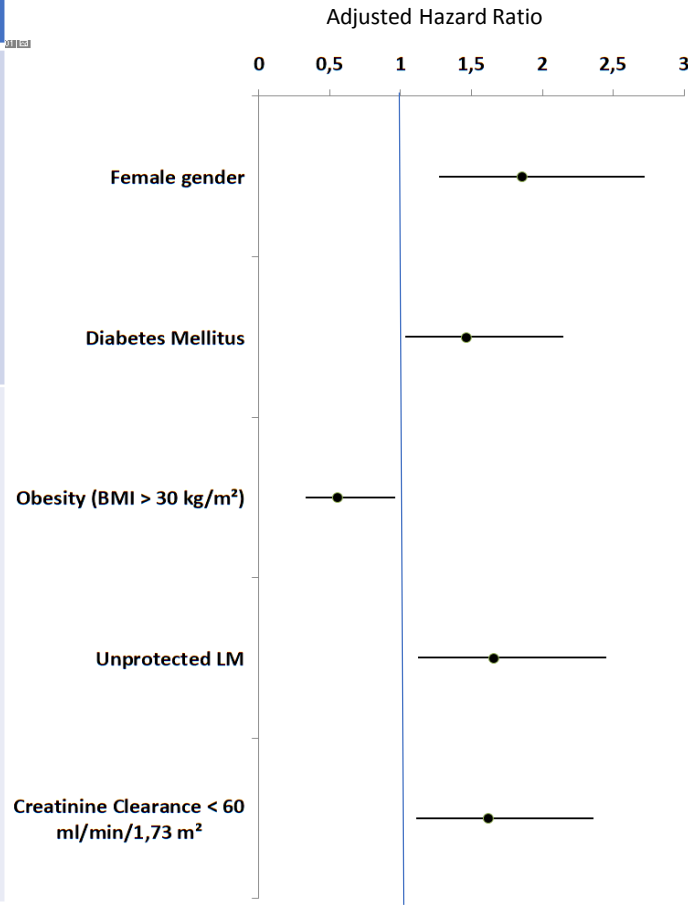


* CV (or unknown cause) death MI Stroke CABG or TLR

- MACE rate : **17.1** for 100 persons / year

Patients characteristics and Predictors of 1-Year MACE

	Crude HR	95% CI	P
Characteristics and medical history			
Female gender	1.82	1.26 – 2.63	0.002
Age (years)	1.01	0.99 – 1.02	0.533
Hypertension	0.82	0.53 – 1.28	0.389
Diabetes	1.41	0.98 – 2.04	0.064
Dyslipidemia	0.97	0.65 – 1.44	0.872
Active smoking	1.07	0.65 – 1.74	0.798
Obesity (BMI > 30 kg/m²)	0.61	0.37 – 1.00	0.052
PVD	1.32	0.87 – 2.03	0.196
Pre-PCI conditions			
PCI indication = STEMI or NSTEMI	1.92	1.32 – 2.79	0.001
Killip class = III/IV	2.15	0.87 – 5.28	0.097
LVEF<35%	1.64	1.04 – 2.60	0.033
Unprotected LM	1.86	1.28 – 2.71	0.001
Coronary extension			
1 vessel	1.00	ref	
2 vessels	1.18	0.67 – 2.09	0.557
3 vessels	2.09	1.24 – 3.54	0.009
Severely calcified bifurcation	1.13	0.78 – 1.64	0.508
Chronic total occlusion	1.15	0.78 – 1.69	0.481
Haemoglobin (g/100 mL)	0.92	0.85 – 0.99	0.040
Impaired Creatinine Clearance (< 60 ml/min/1,73 m²)	1.75	1.21 – 2.52	0.003



Procedural characteristics and 1-Year MACE rate

Data regarding Procedure	Crude HR	95% CI	P
Radial approach	1.22	0.80 – 1.87	0.354
Number of lesions treated with RA			
1	1.00	ref	
2	1.26	0.81 – 1.94	0.304
3+	1.13	0.52 – 2.44	0.758
LM treated with RA	1.28	0.83 – 1.98	0.266
Severely calcified bifurcation treated with RA	0.88	0.59 – 1.30	0.511
Chronic total occlusion treated with RA	0.73	0.34 – 1.57	0.423
Mean number of runs /lesion			
<2	1.00	ref	
2 – 3	1.62	0.92 – 2.86	0.096
4	1.35	0.67 – 2.70	0.396
≥ 5	1.46	0.77 – 2.76	0.243

Data regarding Procedure	Crude HR	95% CI	P
Maximal Burr Diameter (mm)			
1.25	1.00	ref	
1.50	1.13	0.73 – 1.74	0.580
1.75+	0.90	0.51 – 1.57	0.702
Maximal speed (rpm)			
< 160.000	1.00	ref	
160.000-180.000	1.21	0.77 – 1.90	0.409
> 180.000	1.30	0.74 – 2.29	0.354
Mean RA duration (sec) (for 1 lesion treated)			
< 30	1.00	ref	
30 – 60	1.07	0.66 – 1.73	0.795
≥ 60	1.00	0.63 – 1.59	0.989

Key Messages

- This is the first and largest European International registry about modalities of RA use and clinical outcome.
- It provides the possibility of identifying procedural differences related to the use of RA in Europe
- **Clinical and angiographic pre-PCI conditions** are more predictive of MACE than RA procedure at 1-Year clinical follow-up
- **Female gender,Diabetes mellitus,Unprotected Left Main and mid or severe renal failure** are predictive of MACE at 1-Year clinical follow-up in multivariate analysis