



Acute and Long-Term Outcomes of Patients with Impaired Left Ventricular Systolic Function Undergoing Rotational Atherectomy: A Single-Center Observational Retrospective Study

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ABSTRACT

Introduction: Rotational atherectomy (RA) historically was contraindicated in patients with impaired left ventricular (LV) function due to inherent cardio-depressive effects. Contemporary RA practice is less aggressive than traditional RA and no longer withheld from patients with reduced ejection fraction (EF). The aim of this analysis is to explore the outcomes of rotational atherectomy (RA) in patients with reduced left ventricular ejection fraction (LVEF). **Methods:** Patients undergoing RA ($n = 644$) were divided into three groups according to LVEF (severely reduced $\leq 35\%$, $n = 82$;

moderately reduced 36–54%, $n = 170$; and preserved LVEF $\geq 55\%$, $n = 392$).

Results: Compared to patients with preserved LVEF, those with severely reduced LVEF had higher rates of angiographic failure (12.2 vs. 3.3%, $p = 0.003$) and in-hospital major adverse cardiac events (MACE: 9.8 vs. 2.3%, $p = 0.004$) driven by more peri-procedural myocardial infarction (MI: 6.1 vs. 1.5%, $p = 0.049$). In-hospital outcomes were similar between patients with preserved and moderately reduced LVEF. At 5-year follow-up, a stepwise increase in all-cause death was observed with lower LVEF (preserved: 15%, moderately reduced: 23%, severely reduced: 43%; $p < 0.001$). On the other hand, revascularization and MI rates at 5 years were not affected by LVEF.

Conclusions: Compared to patients with preserved LVEF, those with severely reduced LVEF have worse acute outcomes after RA, whereas a moderate reduction of LVEF poses no additional acute hazard after RA. Up to 5 years, the extent of left ventricular dysfunction was associated with a stepwise increase in mortality.

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INTRODUCTION

The role of rotational atherectomy (RA) in contemporary percutaneous coronary

interventions (PCI) is expanding, especially with extension of PCI to more challenging anatomical settings [1]. Severely calcified coronary lesions exist in 6–20% of PCI patients [2, 3]. Calcification makes PCI more complex and increases the risk of complications such as stent under-expansion, restenosis, target lesion revascularization, myocardial infarction (MI), and death [4, 5]. Another challenge for PCI arises from reduced left ventricular ejection fraction (LVEF), which has an adverse effect on acute and long-term outcomes [6, 7].

RA was historically not recommended in patients with impaired LV function due to inherent acute cardio-depressive effects [8]. Contemporary RA practice tends to modify calcified plaques by using smaller burrs and lower rotational speeds rather than aggressive debulking of the lesion. The modern approach is assumed to cause less vessel injury and microvascular obstruction [9] and could therefore be a safer strategy in patients with impaired LV function. Additionally, the expanding use of percutaneous mechanical circulatory support (PMCS) facilitates PCI in complex anatomies and unstable hemodynamic settings and/or impaired LV function [10].

The aim of this analysis is to investigate the outcomes of RA in patients with reduced LVEF.

METHODS

Study Design and Patients

This is a retrospective analysis of patients who underwent RA at a single tertiary center (Heart Centre, Segeberger Kliniken, Bad Segeberg, Germany) between November 2002 and February 2018. Written informed consent was obtained from all patients for analysis of their anonymized data, and data collection was approved by the local ethics committee (Segeberger Kliniken, Bad Segeberg, Germany). The study conforms with the Helsinki Declaration of 1964, as revised in 2013, concerning human and animal rights.

Out of 740 consecutive patients that underwent RA in that time period, 91 presenting with MI and five with no baseline LVEF measurement

were excluded. The remaining patients were divided into three groups based on LVEF: severely reduced LVEF $\leq 35\%$, moderately reduced LVEF 36–54%, and preserved LVEF $\geq 55\%$. The study flowchart is shown in Fig. 1. Echocardiography assessment was according to guidelines utilizing the biplane Simpson's method [11] and was confirmed by LV angiography. Clinical follow-up was obtained either by on-site clinical visit or scripted telephone interview with the patients or their general practitioners.

Procedural Details and Medical Interventions

RA was applied in severely calcified lesions according to the operator discretion as either primary or a bailout strategy in lesions that were uncrossable by balloons or stents. Technical details of RA at our institution have been previously reported [9, 12]. Briefly, for all cases, RA was performed using the CE-marked Rotablator device (Boston Scientific Scimed Inc., Maple Grove, MN, USA). The burr size was selected

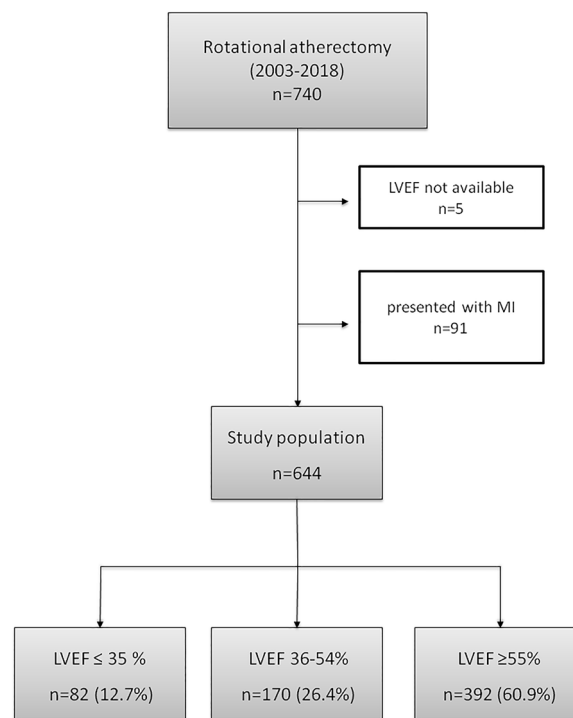


Fig. 1 Study flowchart. *MI* myocardial infarction, *LVEF* left ventricular ejection fraction

aiming at a burr/vessel ratio of 0.5 (max. 0.7 if needed) and rotational speed was 140,000–180,000 rotations per minute (rpm). To prevent slow flow, a continuous intracoronary infusion of unfractionated heparin (UFH), nitroglycerine, and verapamil was used during RA. Prior to RA, patients were treated with 325–500 mg aspirin orally and an oral loading dose of a P2Y₁₂ inhibitor (clopidogrel, prasugrel, or ticagrelor) and peri-procedural anticoagulation with either UFH or bivalirudin was routinely administered. The use of glycoprotein IIb/IIIa inhibitors and PMCS [e.g., with an intra-aortic balloon pump or the Impella system (Abiomed Inc., Danvers, MA, USA)] was at the operator's discretion.

Endpoint Definitions

Angiographic failure was defined as residual stenosis of $\geq 30\%$ and/or less than residual thrombolysis in myocardial infarction (TIMI) III flow at the end of the procedure. Spontaneous MI as well as peri-procedural MI were defined according to the third universal definition of MI [13]. Coronary dissection was defined as any dissection requiring additional stenting beyond the primary lesion. Target vessel revascularization (TVR) was defined as any repeated PCI or coronary bypass of the target vessel. Major adverse cardiac events (MACE) were defined as the composite endpoint of all-cause death, MI, and TVR.

Statistical Analysis

Qualitative variables are summarized as frequencies and percentages, while quantitative variables are summarized as mean \pm SD or median [25th–75th quartiles], depending on variable distribution. Inter-group comparisons were conducted using ANOVA test or Kruskal–Wallis test for continuous variables and by Chi-square test for categorical variables. Survival curves were created using the Kaplan–Meier method, and compared using log rank and Cox hazard regression analyses. For the latter, the hazard ratio (HR) and the 95% confidence interval (CI) are presented.

Multivariable binary logistic regression analysis and multivariable Cox regression analysis were performed using entry criteria of $p < 0.1$ in univariable analysis. Data analysis was performed using SPSS V.24.0 (IBM Corp., New York, NY, USA).

RESULTS

The mean age of the population was 72.3 ± 8.6 years, 75% were males, and LVEF was $52 \pm 13\%$. LVEF was severely reduced in 82 patients (12.7%), moderately reduced in 170 (26.4%), and preserved in 392 (60.9%). The average LVEF in the three groups was 28.9, 46.5, and 60.9%, respectively.

Demographic and Procedural Characteristics

Patients with severely and moderately reduced LVEF were more likely to have three-vessel coronary artery disease ($p < 0.001$) with a higher prevalence of chronic renal impairment ($p < 0.001$), history of MI ($p < 0.001$), history of PCI ($p = 0.043$), and history of coronary artery bypass grafting (CABG, $p < 0.001$). Patients' characteristics are summarized in Table 1.

Target lesions within the reduced LVEF groups were more often ostial ($p = 0.012$), and patients more frequently received PMCS during PCI ($p < 0.001$). Lesion and procedural characteristics are shown in Table 2.

Procedural Outcomes

Patients with severely reduced LVEF had a higher rate of angiographic failure as compared to patients with preserved LVEF [12.2 vs. 3.3%; odds ratio (OR): 4.05, 95% confidence interval (CI) 1.71–9.59, $p = 0.001$]. This was driven by more frequent residual stenosis $\geq 30\%$ (8.5 vs. 2%; OR: 4.48, 95% CI 1.58–12.73, $p = 0.005$) and slow flow (11 vs. 2%; OR: 5.92, 95% CI 2.21–15.84, $p < 0.001$). On the other hand, patients with moderately reduced LVEF did not have an increased rates of angiographic failure as compared to patients with preserved LVEF

Table 1 Patients and demographic characteristics

	LVEF \leq 35% (<i>n</i> = 82 patients)	LVEF 36–54% (<i>n</i> = 170 patients)	LVEF \geq 55% (<i>n</i> = 392 patients)	<i>p</i> value
Age, years	72.5 \pm 8.7	72.93 \pm 8.3	71.9 \pm 8.4	0.813
Male	64 (78.0%)	128 (75.3%)	288 (73.5%)	0.664
BMI, kg/m ²	27.2 \pm 4.4	27.9 \pm 5.0	27.8 \pm 4.7	0.546
LV. Ejection fraction %	28.9 \pm 5.8	46.5 \pm 3.8	60.9 \pm 4.4	< 0.001
Clinical presentation				0.207
Chronic stable angina	76 (92.7%)	144 (84.7%)	341(87.0%)	
Unstable angina	6 (7.3%)	26 (15.3%)	51 (13%)	
Number of diseased vessels				< 0.001
One	7(8.5%)	15 (8.8%)	77 (19.6%)	
Two	19 (23.2%)	39 (22.9%)	124 (31.6%)	
Three	56 (68.3%)	116 (68.2%)	191 (48.7%)	
Diabetes mellitus	26 (32.1%)	64 (37.6%)	133 (34.1%)	0.620
Arterial hypertension	73 (90.1%)	161 (94.7%)	349 (89.5%)	0.136
Dyslipidemia	50 (61.7%)	119 (70.1%)	251 (64.4%)	0.323
Smoking	27 (33.3%)	47 (27.6%)	127 (32.6%)	0.473
Familial history	175 (18.5%)	33 (19.4%)	100 (25.6%)	0.159
Chronic renal impairment (GFR < 60)	19 (32.2%)	40 (24.4%)	42 (11%)	< 0.001
Previous MI	27 (32.9%)	56 (32.9%)	50 (12.8%)	< 0.001
Previous PCI	43 (52.4%)	68 (40.0%)	147 (37.5%)	0.043
Previous CABG	327 (32.9%)	49 (28.8%)	57 (14.5%)	< 0.001

Data are shown as number (percentage), mean \pm standard deviation

BMI body mass index, *LV* left ventricle, *MI* myocardial infarction, *PCI* percutaneous coronary intervention, *CABG* coronary artery bypass grafting

(6.5 vs. 3.3%; OR: 2.02, 95% CI 0.89–4.60, *p* = 0.10). Procedural outcomes are shown in Fig. 2.

On multivariate analysis, angiographic failure was associated with severely reduced LVEF group (OR: 3.36, 95% CI 1.23–9.22, *p* = 0.018) as well as CTO interventions (OR: 2.96, 95% CI 1.04–8.46, *p* = 0.043 (Table 3).

In-Hospital MACE

The rate of in-hospital MACE was 9.8, 3.5, and 2.3% in patients with LVEF \leq 35, 36–54, and \geq 55%, respectively (*p* = 0.004). Compared to patients with preserved LVEF, in-hospital MACE was significantly higher in patients with severely reduced LVEF (OR: 4.60, CI 1.72–12.31, *p* = 0.002) and the difference was driven by more peri-procedural MI (6.1 vs. 1.5%; OR: 4.17,

Table 2 Lesions and procedural characteristics

	LVEF ≤ 35%, (<i>n</i> = 89 lesions)	LVEF 36–54%, (<i>n</i> = 184 lesions)	LVEF ≥ 55%, (<i>n</i> = 421 lesions)	<i>p</i> value
Target vessel				
Left main	12 (13.5%)	30 (16.3%)	40 (9.5%)	0.051
Left anterior descending	29 (32.6%)	74 (40.2%)	219 (52.0%)	0.001
Left circumflex	18 (20.2%)	27 (14.7%)	43 (10.2%)	0.023
Right coronary artery	30 (33.7%)	53 (28.8%)	119 (28.3%)	0.587
Ad hoc PCI	10 (11.2%)	22 (12.0%)	59 (14.0%)	0.673
Chronic total occlusion	9 (10.1%)	19 (10.3%)	23 (5.5%)	0.061
Bifurcation lesion	33 (37.1%)	72 (39.1%)	168 (39.9%)	0.882
Ostial lesion	28 (31.5%)	57 (31%)	89 (21.1)	0.012
ACC/AHA type B2/C*	83 (93.3%)	162 (88.0%)	370 (87.9%)	0.366
Predilatation	80 (90.9%)	163 (88.6%)	375 (89.9)	0.815
Burr sizes				
1.25	20 (24.1%)	47 (26.1%)	103 (24.9%)	0.188
1.5	46 (52.9%)	71 (39.4%)	196 (47.3%)	
1.75	15 (17.2%)	53 (29.4%)	88 (21.3%)	
2	4 (4.6%)	9 (5.0%)	26 (6.3%)	
2.25	1 (1.1%)	0 (0.0%)	1 (0.2%)	
More than 1 burr	13 (14.8%)	23 (12.5%)	73 (17.5%)	0.289
Burr/artery ratio	0.49 ± 0.11	0.50 ± 0.09	0.51 ± 0.10	0.292
Number of implanted stents	1.85 ± 1.3	1.77 ± 0.10	1.92 ± 0.98	0.278
Stent diameter	3.0 ± 0.54	3.1 ± 0.47	3.0 ± 0.49	0.429
Total stent length per lesion	24 [18–40]	30 [18–46]	32 [22–48]	0.131
Post dilatation	59 (67.0%)	115 (62.8%)	260 (63.6%)	0.787
Maximum post-dilatation balloon size	3.5 ± 0.5	3.5 ± 0.6	3.4 ± 0.5	0.485
Type of stent				
BMS	3 (3.4%)	21 (11.4%)	28 (6.7%)	0.036
Early generation DES	28 (31.5%)	83 (45.1%)	173 (41.2%)	0.098
New-generation DES	56 (62.9%)	79 (42.9%)	226 (53.8%)	0.004
Glycoprotein IIb/IIIa inhibitor usage	0 (0.0%)	4 (2.2%)	11 (2.6%)	0.309
Percutaneous hemodynamic assist devices	7 (7.9%)	1 (0.5%)	2 (0.5%)	< 0.001
Impella	2	0	1	

Table 2 continued

	LVEF ≤ 35%, (n = 89 lesions)	LVEF 36–54%, (n = 184 lesions)	LVEF ≥ 55%, (n = 421 lesions)	p value
IABP	4	1	1	
Impella and IABP	1	0	0	
Elective usage of percutaneous hemodynamic assist devices	5(6.1%)	1(0.6%)	0(0%)	< 0.001
Procedural duration (min)	82 [54–109]	68 [49–94]	72 [53–98]	0.499
Amount of contrast material	200 [120–300]	200 [150–280]	200 [150–280]	0.755

Data are shown as number (percentage), median [interquartile range], mean ± standard deviation

PCI percutaneous coronary intervention, * B2/C according to ACC/AHA classification, BMS bare metal stent, DES drug-eluting stent, IABP intra aortic balloon pump

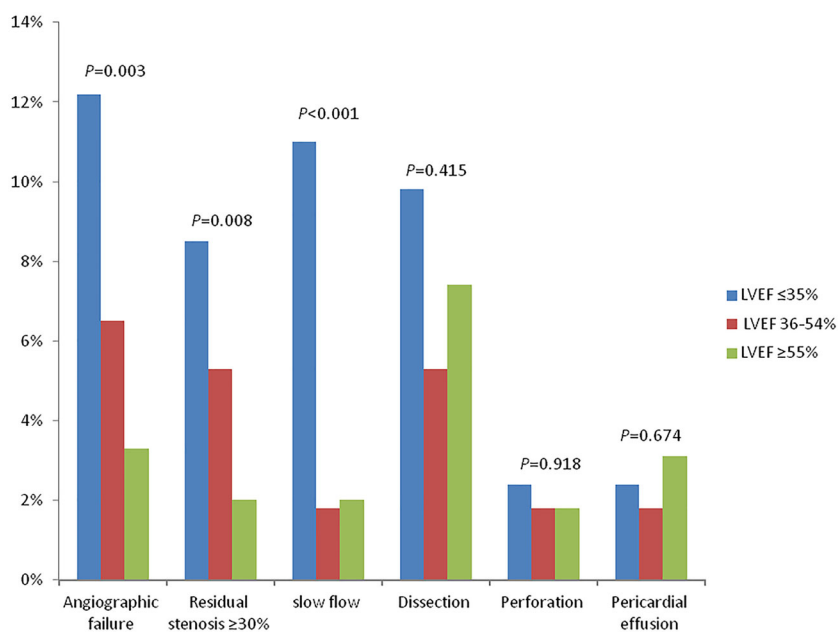


Fig. 2 Procedural outcomes. LVEF left ventricular ejection fraction

95% CI 1.24–14.03, $p = 0.021$) with a trend towards higher mortality (2.4 vs. 0.5%, $p = 0.082$). On the other hand, patients with moderately impaired LVEF did not show increased rates of in-hospital MACE ($p = 0.405$) in comparison to patients with preserved LVEF. The incidence of in-hospital MACE and its

components is displayed in Fig. 3. On multivariate analysis, severely reduced LVEF was the only independent risk factor for in-hospital MACE (OR: 4.39, 95% CI 1.63–11.81, $p = 0.003$) (Table 4).

Table 3 Independent predictors of angiographic failure

	Univariate			Multivariate		
	Odds ratio	95% confidence interval	<i>p</i> value	Odds ratio	95% confidence interval	<i>p</i> value
LVEF ≤ 35%	4.05	1.71–9.59	0.001	3.36	1.23–9.22	0.018
LVEF 36–54%	2.017	0.89–4.60	0.095	1.86	0.71–4.85	0.205
Chronic renal impairment	0.85	0.32–2.25	0.744			
Two-vessel coronary artery disease	2.94	0.68–12.74	0.150			
Three-vessel coronary artery disease	3.42	0.75–15.6	0.112			
Previous MI	1.60	0.75–3.41	0.227			
Previous PCI	2.09	1.05–4.17	0.036	1.35	0.59–3.08	0.474
Previous CABG	1.341	0.61–2.93	0.463			
Target vessel						
Left main	0.38	0.09–1.62	0.192			
Left anterior descending	1.05	0.53–2.08	0.884			
Left circumflex	1.50	0.69–3.29	0.310			
Chronic total occlusion	2.82	1.11–7.17	0.030	2.96	1.04–8.46	0.043
Ostial lesion	0.48	0.18–1.25	0.132			
New-generation DES	2.24	0.93–5.42	0.073	1.96	0.79–4.84	0.146

MI myocardial infarction, PCI percutaneous coronary intervention, CABG coronary artery bypass grafting, DES drug-eluting stent

Evolution of Procedural Outcomes and In-Hospital MACE over the Study Period

In order to investigate the effect of the time factor over the rates of procedural outcomes, patients were divided chronologically into four quartiles according to the timing of the indexed procedures. No significant difference was found between different periods in term of the rates of procedural outcomes as well as in-hospital MACE (Supplementary Table 2).

The distribution of baseline characteristics over the time quartiles are shown in Supplementary Table 1.

MACE at Five Years

The rate of MACE at 5 years was higher in patients with severely reduced LVEF, driven by a higher rate of all-cause death. There was no significant difference across the LVEF groups regarding the rates of MI and TVR (Fig. 4). On multivariate analysis, MACE was no longer significantly associated with severely reduced LVEF (HR: 1.26, 95% CI 0.80–1.99, *p* = 0.310) but rather with chronic renal impairment (HR: 1.50, 95% CI 1.01–2.23, *p* = 0.045) left anterior descending (LAD) artery as the target vessel during the index procedure (HR: 0.68, 95% CI 0.48–0.95, *p* = 0.025) (Table 5). On the other hand, severely reduced LVEF (HR: 2.57, 95% CI

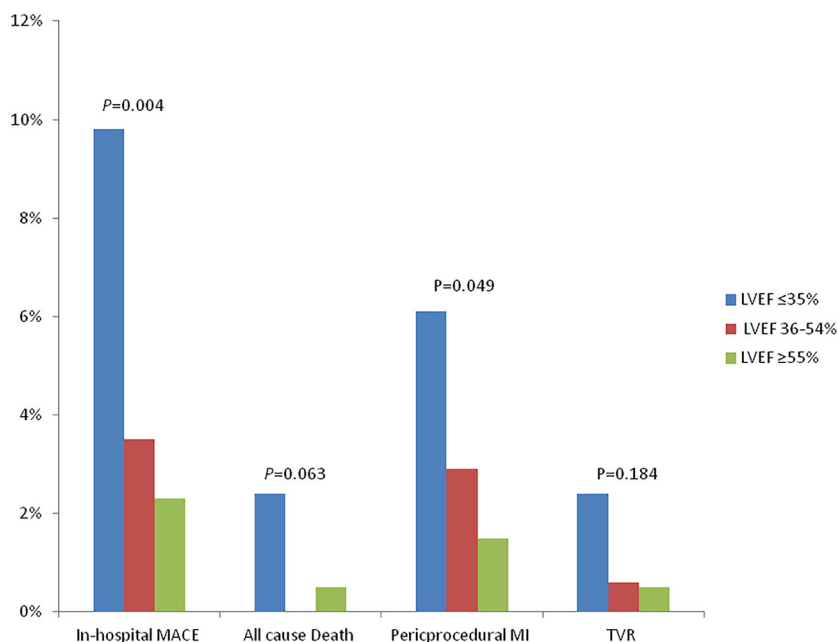


Fig. 3 In-hospital MACE. *MACE* major adverse cardiac events, *MI* myocardial infarction, *TVR* target vessel revascularization, *LVEF* left ventricular ejection fraction

1.38–4.79, $p = 0.003$) as well as in moderately reduced LVEF patients (HR: 1.95, 95% CI 1.15–3.29, $p = 0.013$) and chronic renal impairment (HR: 3.53, 95% CI 2.13–5.82, $p < 0.001$) remained independent predictors of all-cause death (Table 6).

DISCUSSION

The principal findings of this analysis are as follows:

1. RA is safe in patients with moderately impaired LV function but is associated with acute hazards in patients with severely depressed LV function.
2. On the long term, LV function has its well-known effect on mortality with a gradual increase in mortality rates with decreasing LVEF.
3. LV function does not affect TVR rates on the long term after RA

Although LV dysfunction is seen in 10–30% of patients undergoing PCI, patients with impaired LVEF are mostly excluded from contemporary PCI trials [14, 15]. Although recent

ESC practice guidelines recommend revascularization in heart failure patients (LVEF < 35%) with suitable coronary anatomy, this is mainly concluded from the CABG trial [16]. Therefore, the optimal management and the outcomes of patients with impaired LV function still represent a scientific gap in the setting of complex PCIs.

Data on RA in patients with impaired LV function are scarce, but indicate a higher incidence of adverse events in this patient population. In a recent study by McEntegart et al., RA was associated with a type 4a MI rate of 24% as detected by cardiac magnetic resonance (CMR). Moreover, CMR demonstrated myocardial injury in more than half of the patients, and this injury persisted beyond 6 months in 14% of them [17]. Indeed, this is a much higher rate than in our analysis, with a total incidence of peri-procedural MI of 2.5%, but one should consider the usage of the CMR with its high sensitivity and specificity for MI detection in combination with troponin increase. In two other recent studies by Watanabe et al. [18] and Whiteside et al. [19], slow flow was significantly higher in severely reduced LVEF patients

Table 4 Independent predictors of in-hospital MACE

	Univariate			Multivariate		
	Odds ratio	95% confidence interval	<i>p</i> value	Odds ratio	95% confidence interval	<i>p</i> value
LVEF ≤ 35%	4.60	1.72–12.31	0.002	4.39	1.63–11.81	0.003
LVEF 36–54%	1.56	0.55–4.45	0.408	1.45	0.50–4.17	0.494
Chronic renal impairment	1.09	0.36–3.26	0.882			
Two-vessel coronary artery disease	4.164	0.54–31.92	0.170			
Three-vessel coronary artery disease	3.92	0.48–32.33	0.204			
Previous MI	1.08	0.39–2.97	0.880			
Previous PCI	1.17	0.50–2.70	0.722			
Previous CABG	1.06	0.39–2.91	0.910			
Target vessel						
Left main	0.30	0.04–2.17	0.228			
Left anterior descending	0.91	0.39–2.08	0.814			
Left circumflex	0.89	0.30–2.66	0.831			
Chronic total occlusion	2.79	0.91–8.54	0.073	2.49	0.79–7.82	0.119
Ostial lesion	0.61	0.21–1.83	0.380			
New-generation DES	0.70	0.27–1.85	0.476			

MI myocardial infarction, PCI percutaneous coronary intervention, CABG coronary artery bypass grafting, DES drug-eluting stent

[defined as ≤ 35% by Watanabe et al. (*n* = 33) and as ≤ 30% by Whiteside et al. (*n* = 18)].

In line with those studies, we also found that slow flow was more than five-fold higher in patients with severely reduced LVEF (as compared to preserved LVEF) in spite of excluding patients presenting with myocardial infarction from the analysis. These data collectively confirm a strong relationship between LVEF impairment and the risk of slow flow after RA. Previous studies have indeed indicated that coronary flow is closely related to both systolic and diastolic LV function and that slow coronary flow is more frequent in patients with LV dysfunction [20, 21]. It is worth noting that the operators in our study did not react with

glycoprotein IIb/IIIa inhibitors to slow-flow events possibly because of concomitant higher bleeding risks in the cohort with bad ventricular function.

In general, PCI in patients with LVEF < 35% is associated with higher in-hospital mortality rates [22, 23] and is considered as a high-risk PCI [10, 24]. According to the ACCF/AHA/SCAI guidelines for PCI, PMCS is recommended in high-risk PCIs including PCIs in patients with < LVEF 35% [10]. Although not specifically addressed by contemporary practice guidelines, hemodynamic support would theoretically convey an even extra benefit in patients with reduced EF undergoing RA, where the hemodynamic consequences of

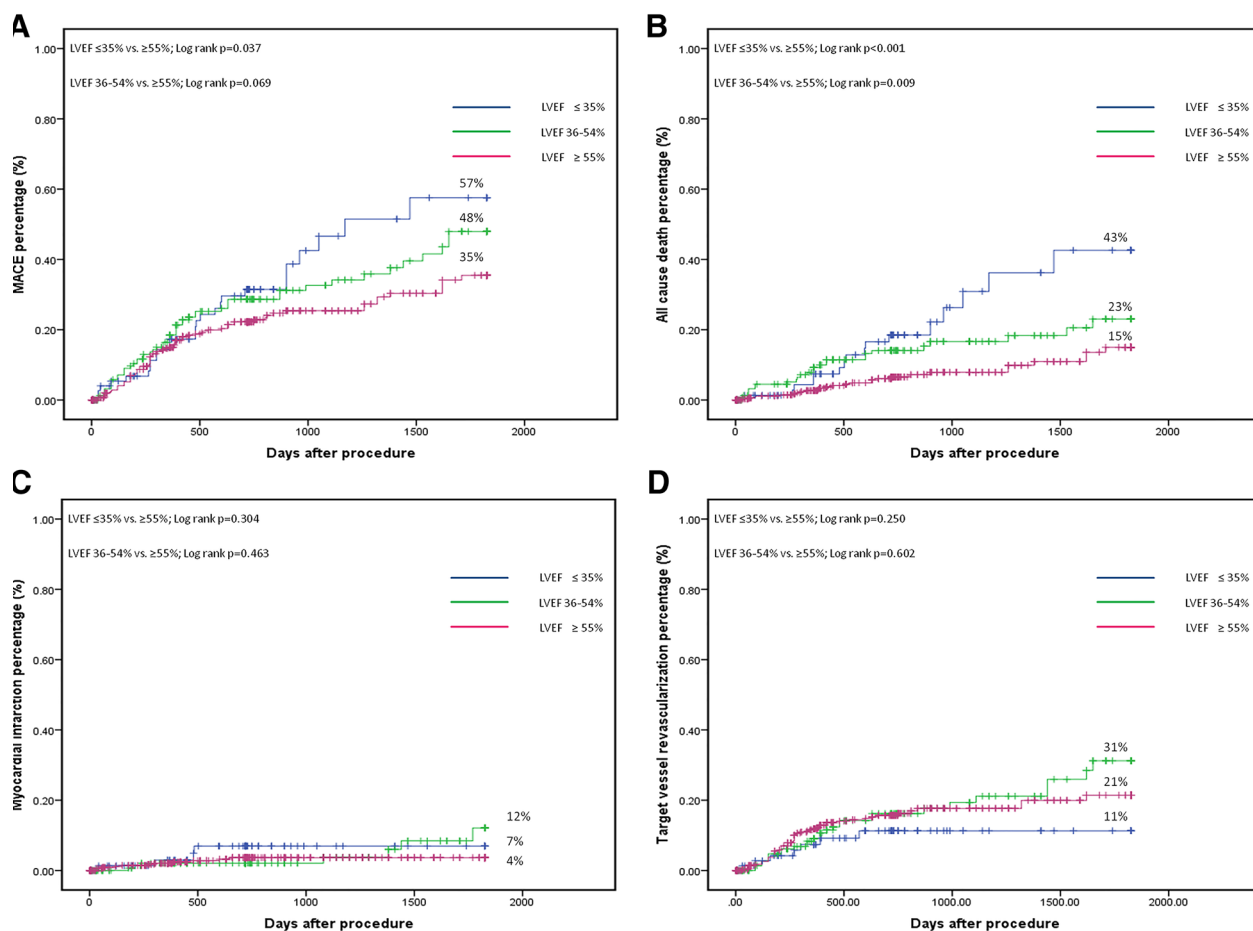


Fig. 4 **a** Kaplan–Meier curve for the cumulative incidence of MACE. **b** Kaplan–Meier curve for the cumulative incidence of all cause death. **c** Kaplan–Meier curve for the

cumulative incidence of MI. **d** Kaplan–Meier curve for the cumulative incidence of TVR

intervention are more profound than in standard PCIs. In our study, PMCS was more frequently used in the severely reduced LVEF group in a total of seven cases, but this relatively small number of patients precluded further valid statistical comparisons.

We observed that there was an association between LV function impairment and higher rates of residual stenosis $\geq 30\%$. Unlike in general PCI populations where excellent angiographic results can still be achieved in patients with reduced LVEF [25, 26], it appears that such favorable procedural outcome is less frequent in the setting of very complex lesions requiring RA. A possible explanation for this observation is that a suboptimal angiographic result is more likely accepted in this group of patients.

Notably, although the acute angiographic results were suboptimal in patients with reduced LVEF, this did not translate to higher rates of TVR in the long term.

As rotational and orbital atherectomy provide comparable clinical outcomes at short-term follow-up [27], we find it useful to compare our results with the outcomes of the ORBIT II study [28]. In contrast to our study, there was no significant difference in the rate of angiographic failure, procedural outcomes, or in-hospital MACE between the reduced LVEF groups (LVEF = 26–40% and LVEF = 41–50%) and preserved LVEF patients (LVEF > 50%) in the ORBIT II. These results should be interpreted with the knowledge that severe tortuous coronary vessels were excluded from the ORBIT

Table 5 Independent predictors of 5-year MACE

	Univariate			Multivariate		
	Hazard ratio	95% confidence interval	<i>p</i> value	Hazard ratio	95% confidence interval	<i>p</i> value
LVEF ≤ 35%	1.56	1.01–2.42	0.047	1.26	0.80–1.99	0.310
LVEF 36–54%	1.42	1.02–1.97	0.040	1.21	0.86–1.71	0.279
Chronic renal impairment	1.57	1.06–2.31	0.023	1.50	1.01–2.23	0.045
Two-vessel coronary artery disease	1.15	0.74–1.78	0.534			
Three-vessel coronary artery disease	1.04	0.64–1.70	0.866			
Previous MI	1.28	0.91–1.79	0.151			
Previous PCI	0.947	0.70–1.29	0.727			
Previous CABG	1.24	0.87–1.75	0.225			
Target vessel						
Left main	0.92	0.59–1.43	0.696			
Left anterior descending	0.61	0.45–0.83	0.001	0.68	0.48–0.95	0.025
Left circumflex	1.45	1.02–2.05	0.039	1.08	0.72–1.64	0.699
Chronic total occlusion	1.19	0.66–2.14	0.563			
Ostial lesion	1.56	1.14–2.13	0.006	1.26	0.90–1.78	0.183
New-generation DES	0.78	0.56–1.10	0.159			

MI myocardial infarction, PCI percutaneous coronary intervention, CABG coronary artery bypass grafting, DES drug-eluting stent

II as well as patients with LVEF ≤ 25%, and that a residual stenosis of less than 50% was considered acceptable. Whether orbital atherectomy is associated with less cardio-depression and microcirculation disturbance in the setting of impaired LV function is unknown, and insights into these questions from ORACLE trial (NCT03021577) are awaited.

In an analysis of more than 230,000 PCI procedures, worsening LVEF independently predicted long-term mortality outcomes [29]. Moreover, the Dynamic Registry investigators observed similar results with reduced LVEF as a predictor of long-term mortality with no significant differences regarding long-term TVR across different LVEF groups [23]. In line with

these observations in global PCI settings, our analysis showed a stepwise increase in 5-year mortality with decreasing LVEF as well as no association between LVEF and TVR. In the same manner, the rate of 1-year cardiac death in ORBIT II study increased as LVEF decreased, while the rate of 1-year TVR was comparable across the LVEF groups. These observations from our series as well as from the ORBIT II indicate that, as in other PCI settings, the long-term survival after RA mainly depends on LV function.

Lastly, considering the long follow-up period of this study. The rates of procedural outcomes as well as in-hospital MACE were equally

Table 6 Independent predictors of 5-year all-cause death

	Univariate			Multivariate		
	Hazard ratio	95% confidence interval	<i>p</i> value	Hazard ratio	95% confidence interval	<i>p</i> value
LVEF \leq 35%	3.08	1.67–5.67	< 0.001	2.57	1.38–4.79	0.003
LVEF 36–54%	2.19	1.31–3.66	0.003	1.95	1.15–3.29	0.013
Chronic renal impairment	3.84	2.36–6.27	< 0.001	3.53	2.13–5.82	< 0.001
Two-vessel coronary artery disease	1.32	0.67–2.60	0.430			
Three-vessel coronary artery disease	0.92	0.42–2.01	0.838			
Previous MI	0.96	0.56–1.65	0.881			
Previous PCI	0.68	0.42–1.11	0.121			
Previous CABG	0.88	0.50–1.56	0.667			
Target vessel						
Left main	0.84	0.42–1.69	0.623			
Left anterior descending	0.78	0.50–1.22	0.272			
Left circumflex	1.18	0.68–2.04	0.563			
Chronic total occlusion	1.142	0.46–2.83	0.774			
Ostial lesion	1.34	0.83–2.17	0.236			
New-generation DES	0.94	0.56–1.58	0.821			

MI myocardial infarction, *PCI* percutaneous coronary intervention, *CABG* coronary artery bypass grafting, *DES* drug-eluting stent, *MACE* major adverse cardiac events, *MI* myocardial infarction, *TVR* target vessel revascularization, *LVEF* left ventricular ejection fraction

distributed among the course of time in our cohort.

In spite of aging of the population as well as increasing rates of chronic renal impairment and repeated PCI over time course, our peri-procedural outcomes did not worsen over time. That in turn emphasizes the evolution in usage of RA in our cohort as the operators became more proficient as time passes.

Limitations

First, this is a single-center retrospective study. Second, although this is the largest study to date investigating RA outcomes in patients with

reduced LVEF, numbers of adverse events remain relatively small.

CONCLUSIONS

Patients with severely reduced LVEF (\leq 35%) undergoing RA had higher rates of angiographic failure (driven by higher residual stenosis and slow flow) and in-hospital MACE (driven by higher peri-procedural MI). Long term, there was a stepwise increase in all-cause mortality with decreasing LVEF, while the reduction of LVEF was not associated with increased TVR rates.

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Compliance with Ethics Guidelines. Written informed consent was obtained from all patients for analysis of their anonymized data, and data collection was approved by the local ethics committee (Segeberger kliniken GmbH, Bad Segeberg, Germany). The study conforms to the Helsinki Declaration of 1964, as revised in 2013, concerning human and animal rights

Data Availability. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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