Clinical Predictors of Mortality Following Rotational Atherectomy and Stent Implantation in High-Risk Patients: A Single Center Experience

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Objectives: Our aim was to assess the procedural success and determine the clinical predictors of postprocedure mortality, following rotational atherectomy (RA) and stenting in high-risk patients. **Background :** RA is mainly used to facilitate stenting in complex lesions. Outcomes involving RA and stenting have been investigated, yet high-risk patients have not been adequately described. **Methods:** Data of 218 consecutive patients who underwent RA were evaluated in a prospective register. Primary endpoints were the angiographic success and long-term mortality. Secondary endpoints were procedural success, consumption of the angioplasty equipment, and periprocedural major adverse cardiac events. The impact of the relevant angiographic and clinical characteristics on long-term mortality was analyzed using uni- and multivariate Cox regression analysis. **Results:** Mean age of the patients was 70 ± 8.2 years, diabetes was present in 44%, and chronic renal failure in 29%. Prior myocardial infarction and three-vessel disease amounted to 42.2% and 32.6%, respectively. Altogether, 52.8% of patients underwent RA after a failed, non-RA intervention attempt, and 30.7% of cases presented as acute coronary syndromes. Angiographic success was 100%, and all patients received stents after RA. Periprocedural major adverse cardiac events occurred in five (2.3%) patients. Postprocedural death was investigated, with a mean follow-up of 36 months. Mortality amounted to 37.2%. Multivariate analysis revealed that left ventricular ejection fraction < 50%, glomerular filtration rate < 60 ml/min, cardiogenic shock, and diabetes were the only independent mortality predictors. **Conclusions:** We have found that RA and stenting is feasible and viable in an elderly high-risk population, with exceptional procedural success and acceptable long-term results. © 2015 The Authors. Catheterization and Cardiovascular Interventions Published by Wiley Periodicals, Inc.

Key words: coronary artery disease; percutaneous coronary intervention; acute coronary syndrome; percutaneous coronary revascularization

INTRODUCTION

The treatment of complex, diffuse fibrotic, or calcified lesions is a serious technical challenge in interventional cardiology. Rotational atherectomy (RA) has emerged as a method of solving such coronary lesions, but is mainly available in tertiary, high-volume centers. RA with subsequent bare metal stent (BMS) or drug-eluting stent (DES) implantation improves the clinical outcomes of patients with calcified coronary artery disease (CAD) [1–8] and procedure-related major adverse cardiac events (MACE) along with mid- to long-term mortality have all been at acceptable levels. Nonetheless, RA is still a technically demanding method requiring scrupulous execution, which may explain why it is seldom used in everyday interventional practice [9–11]. Present-day RA

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is, in our view, thus preserved for diffuse, highly calcified, severely fibrotic lesions: stenoses that seem or prove refractory to balloon manipulation efforts. Both the 2011 American and 2014 European revascularization guidelines classify RA in this manner. Recommendations additionally underline that atherectomy should be in conjunction with the application of coronary stents (RA stenting). Our experience shows that severe coronary pathologies that necessitate RA are rarely seen during percutaneous coronary intervention (PCI) (less than 1% of cases), yet when the need arises, coronary revascularization without this technique often proves a futile attempt. Correspondingly, RA stenting may be performed after a failed conventional non-RA PCI attempt, which can so designate an additional RA indication.

Studies thus far investigating the long-term outcomes have mainly focused on elective indications for RA stenting, with only a relatively small number of acute coronary syndrome (ACS) cases. Furthermore, in the available databases, mainly low- or moderate-risk subjects have been investigated [1–8]. Data regarding the survival after RA stenting in high-risk patients with diffuse CAD presenting with extensive co-morbidities have not yet been sufficiently investigated. This is especially true in cases where patients' extensive co-morbidities deem all other revascularization options unfeasible.

Consequently, the aim of this study was to examine procedural success and long-term mortality outcomes in a large cohort of high-risk, single-center patients treated with RA stenting. Moreover, an attempt was made to identify the clinical predictors of postprocedure mortality.

METHODS

Study Population

RA stenting procedures were carried out on 218 consecutive patients from April 2004 to October 2013. All subjects who underwent RA stenting were prospectively enrolled in our registry, regardless of indication for RA. There were no exclusion criteria in our study. More than half (52.8%) of the RA stenting procedures were carried out promptly (<36 hrs) after a failed non-RA interventional attempt, and, furthermore, an exceptionally large percentage of ACS patients (30.7%) along with presentation of cardiogenic shock cases (6%) were treated. Patient characteristics were assessed, logistic Euroscore II was determined for every subject, and Grace ACS risk model scores were calculated for all ACS patients according to standard protocols. All patients gave written informed consent prior to inclusion in our database, the University Scientific Ethical Board approved of our registry. All details are shown in Table I.

TABLE I. Patient Demographics and Co-morbidities

Patients, n	218
Age (years ± SD)	70 ± 8.2
Male/female, n (%)	157/61 (72/28)
Hypertension, n (%)	203 (93.1)
Hyperlipidemia, n (%)	173 (79.4)
Treated diabetes mellitus, n (%)	96 (44)
Obesity (BMI < 25), n (%)	149 (68.3)
Smoker, n (%)	88 (40.3)
Positive family history, n (%)	79 (36.2)
Peripheral artery disease, n (%)	62 (28.4)
Prior myocardial infarction, n (%)	92 (42.2)
Prior PCI, n (%)	94 (43.1)
Prior CABG, n (%)	34 (15.6)
Coronary artery disease	
Stable angina, n (%)	102 (46.8)
Unstable angina, n (%)	50 (22.9)
NSTEMI, n (%)	56 (25.7)
STEMI, n (%)	10 (4.6)
Cardiogenic shock, n (%)	13 (6.0)
Logistic Euroscore II, median (IQR)	2.1 (1.3–4.3)
ACS Grace in-hospital mortality, median (IQR)	5 (2–18)
ACS Grace 6-month mortality, median (IQR)	14 (8–30)
ACS indication for RA, n (%)	67 (30.7)
Impaired renal function: GFR < 60 ml/min, n (%)	64 (29.4)
Decreased left ventricular function: EF < 50%, n (%)	82 (37.6)
Three-vessel disease, n (%)	71 (32.6)
Medication at discharge	
Aspirin, n (%)	195 (89.4)
Clopidogrel, n (%)	189 (86.6)
Ticlopidine, n (%)	10 (4.5)
Prasugrel, n (%)	19 (8.7)
Beta blocker, n (%)	188 (86.2)
ACE inhibitor/ARB, n (%)	194 (88.9)
Calcium-antagonist, n (%)	44 (20.1)
Statin, n (%)	196 (89.9)

Abbreviations: ACE, angiotensin converter enzyme; ACS, coronary syndrome; ARB, angiotensin receptor blocker; BMI, body mass index; CABG, coronary artery bypass grafting; EF, ejection fraction; GFR, glomerular filtration rate; IQR, interquartile range; NSTEMI, non-ST segment elevation myocardial infarction; PCI, percutaneous coronary intervention; RA, rotational atherectomy; STEMI, ST segment elevation myocardial infarction.

Endpoint Definition

The primary endpoints were the angiographic success of the procedures and long-term all-cause mortality following RA stenting. The secondary endpoints of the study were procedural success and related periprocedural MACE.

Administered Medication

All patients were treated before the procedure with aspirin (300 mg oral loading dose and then 100 mg orally indefinitely) and an ADP receptor blocker, mostly clopidogrel (300 mg oral loading dose and then 75 mg orally for at least 12 months). An intra-arterial cocktail (2.5 mg verapamil, 5,000 IU heparine sodium, and 250 μg nitroglycerine) was given directly in the

TABLE II.   Angiographic and Procedural Data

Angiographic data	
Lesions undergoing RA stenting, n	267
Failed PCI as indication for RA, n (%)	115 (52.8)
Lesion location (%)	
Left main	20.2
LAD	34.0
CX	13.8
RCA	31.8
Angiographic data	
Diameter stenosis (%)	83 ± 11
Reference diameter (mm)	2.8 ± 0.6
Minimum lumen diameter (mm)	0. 8 ± 0.6
Lesion length (mm)	33.1 ± 21.4
Lesion type, n (%)	
Severely calcified	230 (86.1)
Ostial	25 (11.5)
Bifurcational	30 (13.8)
CTO	7 (3.2)
Lesion classification by Ambrose, n (%)	
A/B1	33 (12.3)
B2/C	234 (87.7)
Procedural data	
Radial/femoral, n	112/106 (=1.05)
Thrombus asp. in STEMI, n (%)	8 (3.7)
IABP in cardiogenic shock, n (%)	7 (3.2)
Predilation, n (%)	202 (92.7)
Rota burr/artery ratio	0.6-0.7
DES/BMS ratio	2.9:1
Stent length, mm (mean ± SD)	36.1 ± 21.8
Acute gain, mm (mean ± SD)	1.8 ± 0.5
Postdilatation, n (%)	143 (65.6)
Cutting balloon usage, n (%)	12 (5.5)

Abbreviations: BMS, bare metal stent; CTO, chronic total occlusion; CX, circumflex artery; DES, drug-eluting stent; IABP, intra-aortic balloon pump; LAD, left anterior descending; PCI, percutaneous coronary intervention; RA, rotational atherectomy; RCA, right coronary artery; SD, standard deviation; STEMI, ST-segment elevation myocardial infarction.

radial artery through the sheath in transradial cases. Additional Na-heparin was given 100 IU/kg of body-weight.

RA Stenting Procedure

The arterial access site was chosen according to operator preference and anatomical availability. After engaging the right or left coronary artery with a guiding catheter, a 0.009-inch RA guidewire, the so-called "Rotawire" (Boston Scientific, Maple Grove, MN) was advanced to the distal third of the coronary artery directly or following exchange using a microcatheter or coaxial balloon. RA was performed using the Rotalink Plus system (Boston Scientific). Ablations were performed at 130,000–150,000 rpm, with a standard burr-to-artery ratio of 0.6–0.7. Exceptional care was taken to avoid drops in excess of 5.000 rpm during high-speed ablations. The "traditional rota-cocktail"

(5 mg verapamil and 5,000 U Na-heparin in 1,000 ml saline) was used as lubrication to minimize heat generation and friction of the device during high-speed procedures. In patients presenting with acute ST-segment elevation myocardial infarction (MI) and visible thrombus burdens, pre-RA aspiration was attempted with a 6F compatible aspiration catheter. ACS patients complicated by cardiogenic shock proved exceptionally difficult to manage, as they typically presented with a multitude of co-morbidities, three-vessel disease, advanced age, and extremely calcified coronaries untreatable with conventional methods. Although no guidelines regarding shock and RA with intra-aortic balloon pump use exist, aortic counterpulsation prior to ablation was considered in every appropriate subject. Of these 13 patients, only seven (54%) were anatomically eligible for intra-aortic balloon pump implantation, mostly due to severe peripheral arterial disease. Invasive treatment in cardiogenic shock focused on rapid RA to the apparent culprit lesion(s) and swift attempts to stabilize circulatory parameters. After successful atherectomy and consequent lesion modification, all patients received either BMS or DES devices. All interventions were carried out by one of the three experienced operators. Patients underwent protocol laboratory blood tests before and after RA stenting, and electrocardiogram and cardiac ultrasound examinations were also performed. Optimal medical therapy was initiated in every case following RA stenting. Details of procedures and administered secondary prevention medication are shown in Tables I and II.

Definitions

In-hospital MACE included death from any cause, postprocedure onset MI, emergency coronary artery bypass grafting, and target vessel revascularization. New-onset MI in elective cases with negative preintervention biomarkers was defined as creatine kinase muscle-brain type elevation greater than two times of upper normal level with Q waves or without Q waves on the electrocardiogram 24 hrs after surgery. Angiographic success was defined as residual stenosis of <30% after stent implantation along with thrombolysis in myocardial infarct flow grade III at the end of the procedure. Procedural success was defined as angiographic success without a MACE event.

Angiographic Analysis

Quantitative analysis of the angiographic images was performed using the digital caliper method by General Electric (Fairfield, CT). The segment analyzed included the stent and the 5 mm proximal and distal overhang of the stented segment. The percentage

diameter stenosis, minimum luminal diameter, reference vessel diameter, and lesion length were measured at baseline and immediately after the RA stenting procedure. Acute gain was defined as the increase in minimum luminal diameter immediately after intervention.

Follow-up Details

Clinical and laboratory data during hospitalization was prospectively recorded. Follow-up (FU) of patients was clinically driven, with physician office visits at least once a year. Mortality data were collected and verified via official death records of the Hungarian National Health Insurance, which ensured accuracy. Thus, no patient was lost during the FU period. Duration for overall survival was measured from the date of the initial RA to the date of confirmed death or of last live contact. FU ended on October 23, 2013. Mean FU time was 36 months (range, 1–87 months). A total of 137 (62.8%) patients were alive at the database termination time point (October 23, 2013). Hence, the remaining 81 (37.2%) patients deceased during the FU period. This amounts to more than one-third of the entire study population and the high number of endpoint events enabled proper statistical evaluation. Consequently, no other long-term endpoints were studied.

Statistical Analysis

All continuous variables studied were expressed as mean ± standard deviation or median with interquartile ranges, whereas categorical variables were expressed as percentage. Survival curves were plotted using the Kaplan–Meier method and compared with the log-rank test. We used the univariate and multivariate Cox regression analysis to evaluate the effects of the studied parameters on mortality. Determination of these modifiers (risk factors) was carried out by selecting variables with probabilities of $P < 0.10$ from the univariate Cox regression analysis. These were further examined with the multivariate regression model to assess independence. The internationally accepted probability ($P < 0.05$) was chosen for significance level. Where eligible, calculations of hazard ratios (HRs) were also carried out, using a confidence interval of 95%. Data were stored in Microsoft Excel 2010 and analyzed with the SPSS statistical software (version 20.0.1, SPSS, Chicago, IL).

RESULTS

Demographic and Clinical Data

Patient demographics and classified co-morbidities are shown in Table I. More than half (52.8%) of the RA stenting procedures were carried out promptly (<36 hrs) after a failed non-RA interventional attempt, and an exceptionally large percentage of ACS patients (30.7%), along with presentation of cardiogenic shock cases (6%), were treated. Collected and calculated data elucidation, after Cox univariate analysis, showed that patient age > 70 years ($P = 0.615$), male gender ($P = 0.349$), peripheral arterial disease ($P = 0.680$), dyslipidemia ($P = 0.568$), body mass index of >25 kg/m^2 ($P = 0.317$), prior MI ($P = 0.134$), prior coronary artery bypass grafting ($P = 0.732$), left main stem intervention ($P = 0.245$), and radial approach RA ($P = 0.809$) did not have any significant impact on all-cause mortality.

Procedural and Angiographic Data

Table II contains the data from the quantitative angiographic analyses. The reference vessel diameter was 2.8 ± 0.6 mm. Residual stenosis after the procedure was $10\% \pm 3\%$. The lesion length at baseline was 33.1 ± 21.4 mm, and 165 (75.7%) of the lesions were longer than 20 mm. After final stent implantation, the acute gain was 1.8 ± 0.5 mm.

Of the 218 patients involved in our assessment, all underwent successful RA and stent implantation. Angiographic success was 100%, and all patients received stents after the RA procedure. Implanted DES and BMS ratio amounted to 2.9:1. Procedural success was 97.7%. The consumption of angioplasty equipment is also summarized in Table II.

In-hospital MACE and Long-term Mortality

In-hospital MACE was found to be 2.3%, with periprocedural death occurring in four cases. The following variables, with respect to all-cause mortality after analysis, gave a P-value of <0.1 with Cox univariate analysis: hypertension ($P = 0.081$), diabetes mellitus ($P = 0.01$), glomerular filtration rate (GFR) of <60 ml/min ($P < 0.001$), ejection fraction (EF) of <50% ($P < 0.001$), prior PCI ($P = 0.072$), three-vessel disease ($P = 0.057$), RA stenting performed in ACS setting ($P = 0.006$), RA stenting done in cardiogenic shock ($P < 0.001$), and RA stenting following failed conventional PCI ($P = 0.035$). These nine factors were further studied using multivariate Cox regression models. Independent risk factors of all-cause mortality following RA after further analysis proved to be: cardiogenic shock upon presentation prior to RA ($P = 0.004$, HR: 3.306), GFR < 60 ml/min ($P < 0.001$, HR: 2.557), EF < 50% ($P = 0.005$, HR: 1.938), and diabetes mellitus ($P = 0.016$, HR: 1,819; Table III). HR and confidence interval were not calculated for parameters not showing statistically significant independence.

TABLE III.   Uni- and Multivariate Cox Regression Data Analysis

Variable	Univariate analysis (p-value)	Multivariate analysis (p-value)	Hazard ratio	95% confidence interval
Cardiogenic shock at RA	<0.001	0.004	3.306	1.468–7.448
GFR < 60 ml/min	<0.001	<0.001	2.557	1.611–4.059
Ejection fraction < 50%	<0.001	0.005	1.938	1.222–3.074
Diabetes	0.010	0.016	1.819	1.116–2.966
ACS indication for RA	0.006	0.414		
Failed PCI as indication for RA	0.035	0.138		
Prior PCI	0.072	0.185		
Three-vessel disease	0.057	0.563		
Hypertension	0.081	0.083		

Abbreviations: ACS, acute coronary syndrome; GFR, glomerular filtration rate; PCI, percutaneous coronary intervention; RA, rotational atherectomy.
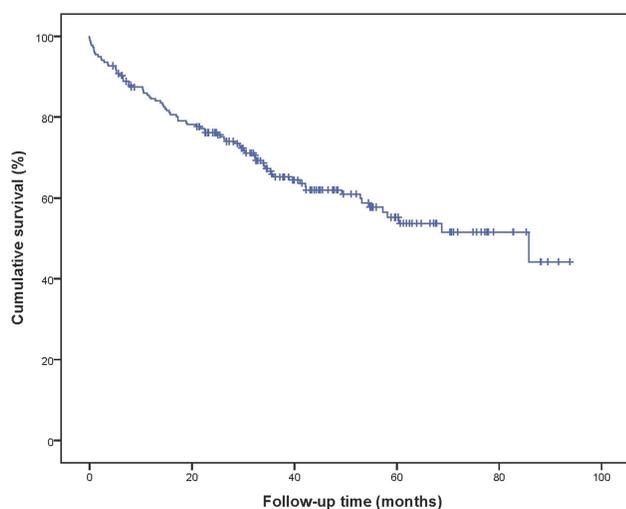
Fig. 1. Kaplan–Meier survival curve of total study population ($n = 218$). Cumulated survival curve of all registry patients undergoing RA stenting, during the FU period. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Our overall mortality data are presented as Kaplan–Meier survival curves (Fig. 1). Additional curves were plotted to assess survival data for every independent risk factor: diabetes mellitus, decreased GFR (<60 ml/min), decreased EF ($<50\%$), and cardiogenic shock upon presentation (Fig. 2A–D). Values of the log-rank test comparison showed a significantly decreased survival rate for each patient presenting with either of the four independent risk factors of mortality as compared with the rest of the study population. Our calculated P-values are as follows: $P < 0.001$ for cardiogenic shock upon presentation, $P < 0.001$ for GFR < 60 ml/min, $P < 0.001$ for EF $< 50\%$, and $P < 0.009$ for diabetes mellitus.

DISCUSSION

RA in the coronary circulation system is used to treat severe fibrocalcific and otherwise undilatable or uncrossable lesions, bifurcational disease involving the side branch ostium, and calcified stenosis involving the left main stem or right coronary ostium [12–15]. As defined in the latest American and European revascularization guidelines, the main goal of contemporary RA is to modify and debulk severe intracoronary masses in lesions, which result in superior lumen gains and thus eventually contribute to better stent deployment and expansion. Pristine stent expansion is associated with lower restenosis and stent thrombosis rates. Fujimoto et al. [16] published improved MACE and stent thrombosis rates in patients who presented with calcified coronary disease and/or chronic hemodialysis and underwent RA stenting as compared with subjects treated with standard balloon angioplasty and stent implantation.

DES implantation following RA show better long-term results than that of BMS use. Rathore et al. [5] compared the restenosis, success rate, and the in-hospital outcomes after RA with BMS versus DES implantations and have found significantly better restenosis rates following DES implantation (11% vs. 28.1%, $P < 0.001$). Benezet et al. [1] published total cardiac death, target lesion revascularization, and MI incidence rates of up to 4.9%, 3.9%, and 8.8%, respectively, at 15 months FU with RA stenting using DES devices. Abdel-Wahab et al. [2] also found promising long-term results following RA stenting with DES systems in a large patient database. Despite all these promising trials, however, ACS and high-risk patients were either excluded from different studies or were not sufficiently examined.

Rotational Atherectomy in Different Clinical Situations and High-Risk Patients

Our study differs from the aforementioned study populations in many regards and offers novel information and new insights, as our data focuses on long-term mortality involving an exceptionally high-risk, elderly patient population, following RA stenting (age 70 ± 8 years, 44% diabetes, 29% chronic renal failure, 30% ACS cases, and 32% three-vessel disease subjects).
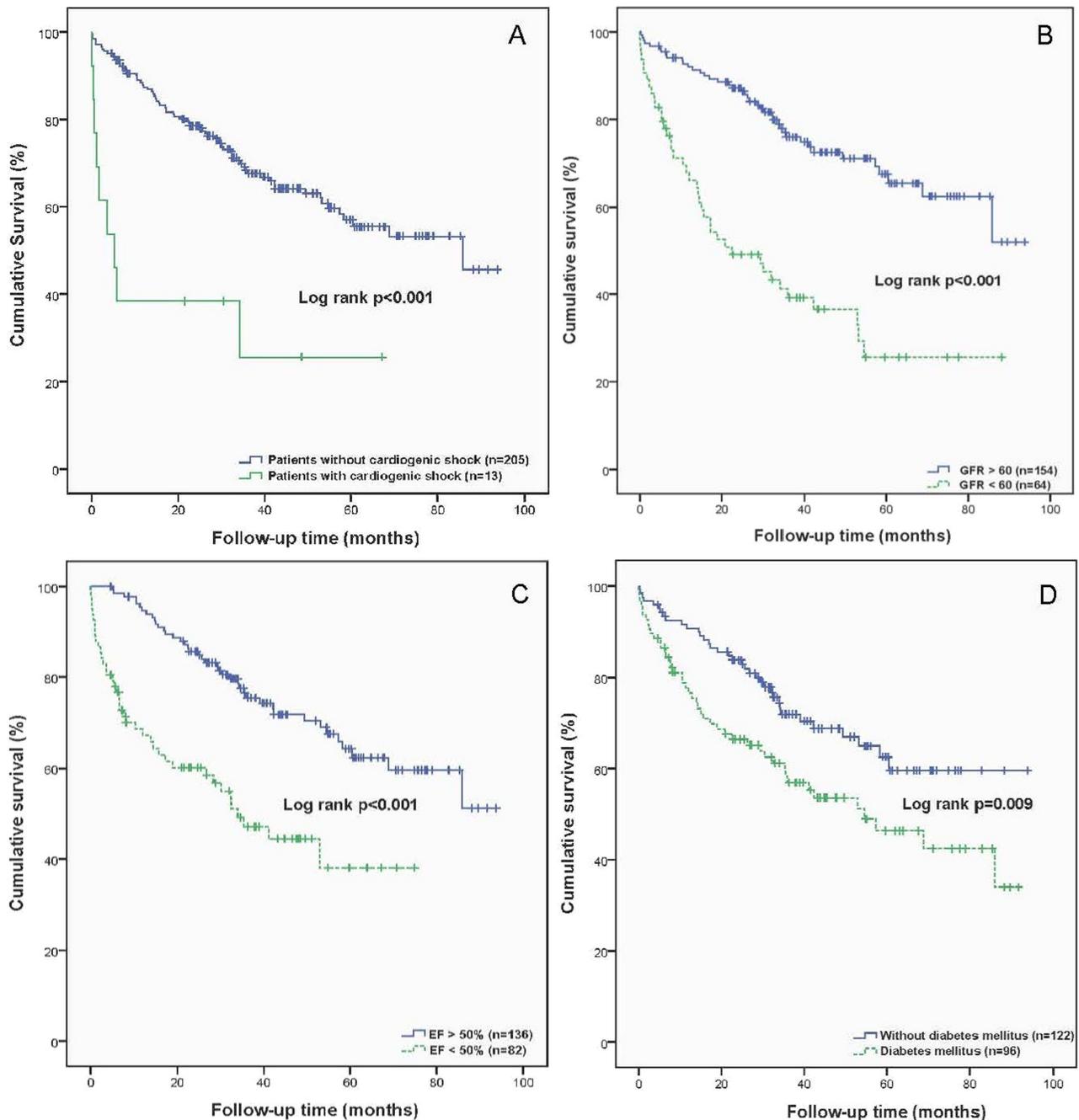
Fig. 2. Kaplan–Meier survival curves according to different independent risk factors. (A) Survival data for patients presenting with or without manifest cardiogenic shock during RA stenting. (B) Survival data for patients with decreased and normal kidney funtion. (C) Survival data for patients with normal and decreased left ventricular function. (D) Data on patient survival, with patients treated for and those without diabetes. Abbreviations: DM, diabetes mellitus; EF, ejection fraction; GFR, glomerular filtration rate. [Color figure can be viewed in the online issue, which is available at wileyonline library.com.]

Accordingly, the majority of our patients underwent RA stenting in crucial, real-world conditions. Many subjects, especially ACS RA stenting and three-vessel disease cases were performed as last means of revascularization. Co-morbidities greatly increased potential surgical adverse event risk, as estimated by logistic Euroscores. Frequency of high GRACE score ACS in our population was also considerable (30.7%), nearly three times more, than in any other similar clinical studies. RA stenting was also performed in 13 (6%)

cases, when subjects with ACS presented in manifest cardiogenic shock. Additionally, more than half of our RA cases involved patients who were promptly transferred from other non-RA PCI centers for atherectomy following unsuccessful conventional PCI. All these patients presented following excessive contrast material load and X-ray burden, not to mention prolonged hospitalization and the necessity of repeat, RA stenting-based PCI.

Thus, the main message of our work is twofold. On one hand, to prove that RA stenting is a feasible and viable option even in seemingly hopeless cases, when there is genuinely no other clinical option left. Angiographic and procedural success were outstanding (100% and 97.7%), although a wide array of interventional devices were necessary during procedures, especially in ACS cases and three-vessel disease lesions.

On the other hand, we have also proven that long-term FU of our high-risk, elderly RA stented patients yield acceptable all-cause mortality data as compared with that in other databases [1–6].

Clinical Predictors Influencing Mortality

Cardiogenic shock in ACS is a well-known predictor of short- and long-term mortality. In accordance to this, our database also showed that cardiogenic shock is a very strong and independent clinical predictor of mortality in our patient population. Another strong and independent modifier of survival was decreased renal function. This fact is also well known for patients, following coronary interventions [17]. Accordingly, in our database, renal function impairment (GFR < 60 ml/min) was a strong contributor of increased long-term death rates. Two more independent clinical predictors of mortality were observed in our database: decreased left ventricular EF and diabetes. Decreased left ventricular EF has previously been found to be an independent risk factor of mortality following conventional PCI and RA stenting [2,18]. In fact, an inverse relationship has been noted in heart failure between left ventricular EF and mortality. Consequently, it is reasonable that in our RA stented patient population, decreased left ventricular EF also presented as a significant independent risk factor of mortality. Diabetes, even when well treated, is a well-known risk factor of cardiovascular disease, especially CAD, and shows poor outcomes following conventional PCI [18,19]. Our data, again, concur in this regard.

We have to stress, however, that among other things RA stenting following a failed conventional PCI and ACS as indication for RA alone did not influence mortality outcome of RA-stented patients in our population.

Limitations of the Study

The database reflects the results of a single high-volume center. Furthermore, in our study population, use of stents was not uniform, as both BMS and DES devices were implanted, according to the clinical situation at hand and operator preference.

CONCLUSION

In summary, we have found that RA stenting is a feasible and viable option in an elderly and high-risk population, with exceptional procedural success and acceptable long-term results. Analysis of our database revealed four important independent clinical predictors of long-term mortality: cardiogenic shock prior to RA stenting, decreased GFR (<60 ml/min), decreased left ventricular EF (<50%), and diabetes.

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