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Predictors of major adverse events after stent implantation for atherosclerotic renal artery stenosis

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ABSTRACT

Objectives: Atherosclerotic renal artery stenosis (ARAS) is the most frequently seen cause of secondary hypertension (HT). ARAS associated with adverse cardiovascular events independently of other traditional cardiovascular risk factors, and increased mortality. Percutaneous transluminal renal arterial stenting (PTRS) is important methods in ARAS treatment. The aim of this study was to investigate major adverse events (MAE) and potential predictors in patients undergoing PTRS for ARAS by evaluating variables before and immediately after the procedure, including the SYNTAX score.

Methods: One hundred and five consecutive patients who underwent PTRS over a period of approximately 10 years were included in our study. Patients were divided into two groups, MAE negative (-) and MAE positive (+), according to the occurrence of MAE. After comparing both groups with difference tests, independent predictors were investigated with univariate and multivariate Cox regression analysis. Afterwards, Receiver Operating Characteristics (ROC) analysis was performed on independent predictors.

Results: The average age of the patients was 63.32±11.62 years (range: 30-83 years) and 52 (49.5%) of them were male. Sixty-two patients constituted the MAE (-) and 43 the MAE (+) groups. In multivariate Cox regression analysis, chronic obstructive pulmonary disease (COPD), left ventricular ejection fraction (LVEF), and the total number of antihypertensives after the procedure were identified as independent predictors. As a result of the ROC analysis, a cutoff value of ≤55% for LVEF was determined to have area under the curve (AUC) 0.733, 69.8% sensitivity, and 77.42% specificity (P<0.001). The use of more than 3 antihypertensive drugs after the procedure was found to have AUC 0.624, 34.88% sensitivity, and 82.26% specificity (P=0.023).

Conclusions: LVEF, COPD, and the postprocedural total number of antihypertensives were independent predictors for MAE seen after PTRS in ARAS patients. These predictors can be used to estimate the risk in these patients. To be able to prevent adverse events, it is important that patients with these markers are treated and followed up more closely.

Keywords: Renal artery stenosis, atherosclerosis, hypertension, stent, adverse events

Atherosclerotic renal artery stenosis (ARAS) is the most frequently seen cause of secondary hypertension (HT), and is responsible for approximately 90% of all renal artery stenosis (RAS) cases [1, 2]. RAS can result in adverse events such as resistant HT, progressive impairments in renal functions and cardiac destabilisation syndromes [3, 4]. ARAS has also been associated with adverse cardio-

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vascular events independently of other traditional cardiovascular risk factors, and increased mortality [5].

Percutaneous transluminal renal arterial angioplasty and stent procedures (PTRA and PTRS) are important methods in ARAS treatment [6]. Various studies have been conducted of the clinical outcomes of patients who have undergone PTRS procedure for ARAS [7, 8]. In studies that have been conducted to investigate predictors of adverse events and mortality in patients with ARAS, different variables have been investigated in different cohorts, and naturally different results have been reported. This has led to a state of uncertainty. In a previous study of patients presenting with myocardial infarction (MI) with ST-elevation, a correlation was determined between the SYNTAX (Synergy Between Percutaneus Coronary Intervention with Taxus and Cardiac Surgery) score and RAS [9]. However, the potential relationship between coronary artery disease (CAD) complexity evaluated with the SYNTAX score, and long-term adverse events after PTRS procedure is unknown.

The aim of this study was to investigate major adverse events and potential predictors in patients undergoing PTRS for ARAS by evaluating variables before and immediately after the procedure, including the SYNTAX score. It was thus aimed to contribute to the literature by determining high-risk patients in this patient group.

METHODS

Study Design and Population

Approval for the study was granted by the Local Ethics Committee. This was a retrospective study conducted at a single high-volume center. The study population was defined as patients who underwent a PTRS procedure between 1 January 2014 and 1 June 2024. The data required were obtained from the electronic hospital information system, archived records,

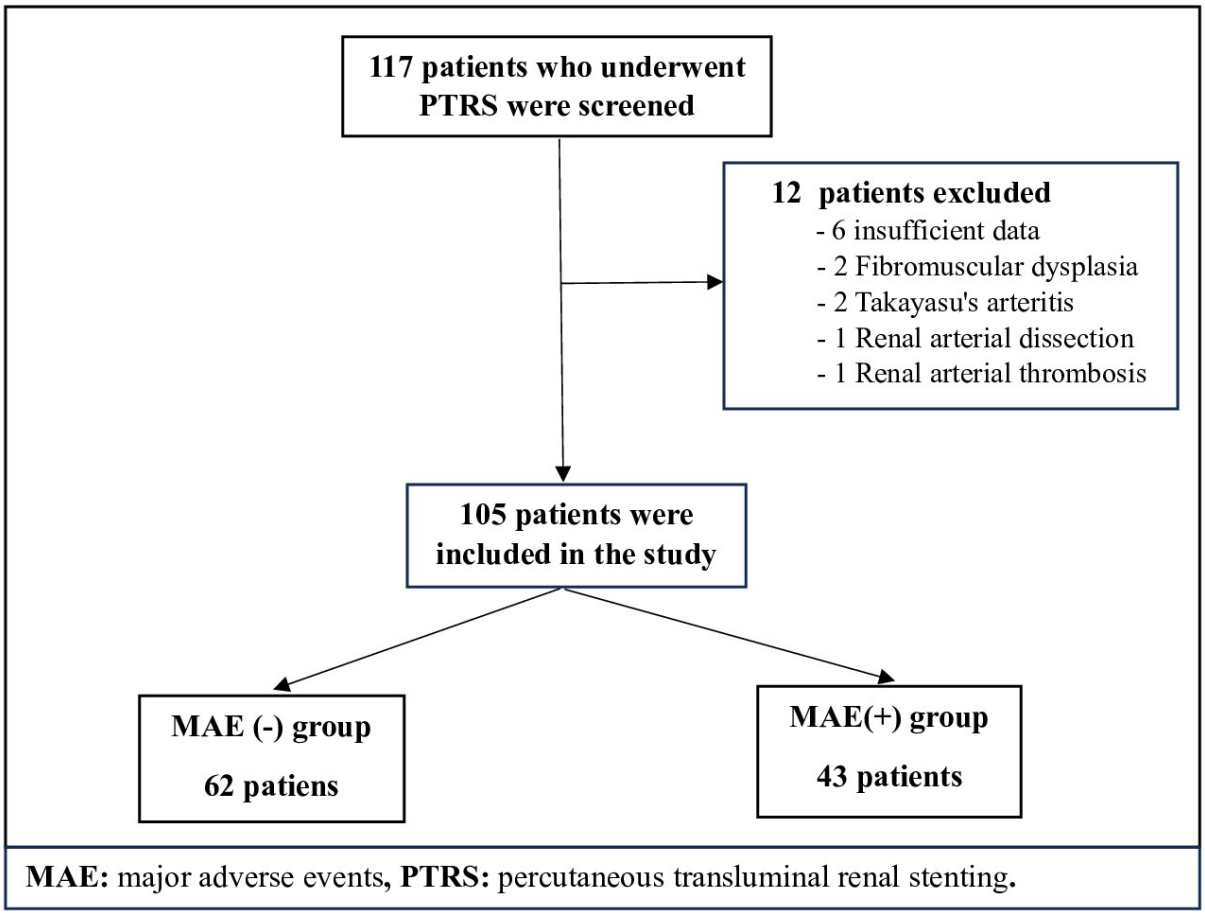

Fig. 1. Study flowchart.

telephone or face-to-face interviews with patients and their relatives, the national health system, and the death notification system records. From the initial inclusion of 117 consecutive patients who underwent PTRS, following the implementation of exclusion criteria, 105 patients were included in the study for analysis (Fig. 1. Study flow chart). The study inclusion criteria were defined as age >18 years, and having undergone PTRS because of resistant HT, reduced renal function, or "flash" pulmonary oedema, associated with ARAS.

The study exclusion criteria were defined as: (i) PTRS performed for a RAS reason other than ARAS, (ii) PTRS performed following renal transplant, (iii) total renal artery occlusion, (iv) incomplete or unreliable data for the pre-procedure and follow-up periods, (v) kidney diameter <7 cm, target renal artery diameter <4 mm, (vi) estimated glomerular filtration rate (eGFR) <10 mL/min/1.73m^2, (vii) previous target vessel revascularisation (TVR), and (viii) receiving chronic renal replacement therapy.

First Evaluation and Laboratory Analysis

Before the procedure, all the patients underwent detailed evaluations including anamnesis and physical examination, then fasting blood tests were performed for the necessary laboratory analyses. HT was defined as systolic blood presssure >140 mmHg and diastolic blood pressure >90 mmHg. Patients with high blood pressure measurements recorded despite the use of at least 3 anti-hypertensives, including one diuretic, were accepted as resistant HT patients. On discharge after the procedure, full cure was accepted as blood pressure <140/90 mmHg without medication, and the procedure was accepted as beneficial when there was blood pressure <140/90 mmHg with a decrease or no change in the number of drugs, or a decrease in diastolic pressure of ≥15 mmHg [10].

Patients who were already receiving statin treatment or had non-HDL cholesterol level >130 mg/dL were accepted as hyperlipidemia. The demographic and clinical data, and basal laboratory findings were recorded for all the patients. The eGFR in this study was calculated from the equation of Modification of the Diet in Renal Disease (MDRD) [11]. The diagnosis of contrast nephropathy (CN) was defined as an increase of over 0.5 mg/dL or 25% in the creatinine value within 48-72 hours after contrast exposure [12]. The antihypertensive drugs used by patients before and after the procedure were recorded.

Transthoracic Echocardiography and Electrocardiography

Before the procedure, two-dimensional (2D) transthoracic echocardiography (TTE) was performed on all patients by cardiologists who were experienced in the field of echocardiography and blinded to the patient data. The left ventricle ejection fraction (LVEF) and other parameters examined on the 2D echocardiography device (Epiq 7c Ultrasound System, Philips, Andover, MA, USA) before the procedure were recorded. The findings were evaluated according to the recommendations in the American Society of Echocardiography (ASE) guidelines [13]. All the echocardiographic data used in this study were recorded during the scanning by cardiologists blinded to the patient data.

Before the procedure, 12-derivation electrocardiograms (ECG) at 25mm/sec speed and 10mm/mV were obtained from all the patients. The Socolow-Lyon Index (V1S+V5/V6 longest R wave> 35 mm) was used as the criteria for left ventricle hypertrophy [14].

Interventional Angiography and Renal Stent Procedure

The final decision for PTRS was made without exception by evaluating the invasive coronary angiography and renal angiography as they are often used together for the definitive diagnosis of ARAS patients who have initially been diagnosed using other imaging methods (renal duplex ultrasonography, computed tomography, magnetic resonance imaging angiography). Patients who had previously experienced acute coronary syndrome were accepted as previous MI. The Syntax scores of the patients were obtained by two experienced invasive cardiologists, blinded to the clinical characteristics of the patients, using a web-based online calculator (www.syntaxscore.com, versiyon 2.1).

The PTRS decision was made by at least two experienced interventional cardiologists with the detection of ≥70% unilateral or bilateral ARAS as a result of visual and quantitative angiographic evaluation. Patients were administered 100 mg acetyl saliycylic acid (ASA) and 300 mg clopidogrel on the day before the procedure, or 300 mg ASA and 600 mg clopidogrel loading on the day of the procedure. Dual antiplatelet

therapy has been recommended for at least 6 months and ASA indefinitely. The procedure was performed by an experienced interventional cardiologist via the femoral arteries in almost all cases, and in a very small proportion via the left radial artery. Heparin at a dose of 5000-10000 IU bolus was administered to the patients before the procedure. PTRS was performed using standard techniques.

After the placement of a suitable guide catheter to the renal artery, the lesion has passed with 0.014 or 0.018 guidewires. Then, if necessary, first PTRA was performed, then a self-expanding, bare metal renal stent was implanted with a balloon of diameter and length appropriate to the lesion. When PTRA was not required, the renal stent was applied directly. If there was seen to be a geographical mismatch or dissection on the images obtained after the procedure, a second renal stent was implanted. In patients with bilateral ARAS, the procedure was performed on the other renal artery in the same session. The procedure was accepted as technically successful if there was <20% residual narrowing remaining after the intervention. All the patients were followed up under the best personalised medical treatment.

Major Adverse Events

The patients were hospitalised for at least 48 hours after the procedure then followed up in the polyclinic at regular intervals. Major adverse events (MAE) during the follow-up period were defined as all-cause mortality, acute coronary syndrome, stroke, hospitalisation because of heart failure, the requirement for renal replacement therapy or permanent renal replacement therapy, renal transplant treatments because of progressive renal dysfunction, and target vessel revascularisation (TVR). The total follow-up period and the time to the development of MAE were recorded.

Statistical Analysis

All the analyses of the study data were performed using MedCalc 20.0.4 software (MedCalc Software Ltd, Ostend, Belgium). The patients were separated into two groups as those who developed and did not develop MAE, and these groups were compared. Conformity of continuous variables to normal distribution was assessed with the Kolmogorov-Smirnov test. Descriptive statistics were stated as mean±standard deviation (SD) values for data showing normal distribution and as median (25^{th}-75^{th} percentile) values for those not showing normal distribution. Categorical variables were stated as number (n) and percentage (%). The two groups (MAE positive and negative) were then compared using the Independent Samples t-test for normally distributed continuous variables, and the Mann Whitney U-test when distribution was not normal. In the comparisons of categorical variables, the Chi-square test or Fisher Exact test was used, as appropriate. For the variables found to be significant in the difference tests, univariate Cox regression analysis was performed. Then, variables with significant p values in the univariate analysis were included in the multivariate analysis. Receiver Operating Characteristics (ROC) analyzes were performed on continuous variables for independent predictors identified in multivariate Cox regression analysis. A value of $P<0.05$ was accepted as statistically significant in all the statistical analyses.

RESULTS

Evaluation was made of 105 patients comprising 52 (49.5%) males and 53 (50.5%) females with a mean age of 63.32±11.62 years (range: 30-83 years). MAE developed in 43 (41%) patients (MAE + group) and did not develop in 62 (59%) (MAE - group). The procedure was performed because of resistant HT in 98 (93.3%) patients, decreasing renal functions in 4 (3.8%), and recurrent "flash" pulmonary oedema in 3 (2.9%).

The demographic characteristics of the patients, blood pressure values before the procedure, and drugs used are shown in Table 1.

The total follow-up period was mean 39 months (range: 22-72 months) and the mean time to the development of MAE was 35 months (range:13-56.5 months). Of the 43 events that occurred in the MAE + group, 29 were all-cause mortality. The other 14 MAE were 6 (13.9%) acute coronary syndrome, 4 (9.3%) stroke, 2 (4.6%) patients started hemodialysis, 1 (2.3%) had renal artery stent thrombosis, and 1 (2.3%) TVR because of renal artery in-stent restenosis. When the causes of death were examined, the causes of the 29 deaths were determined to be multiple organ failure developing due to chronic renal failure in 8 (27.5%) cases, acute coronary syndrome in 5 (17%), COVID-

Table 1. Comparison of baseline demographic and medication data of MAE negative and positive groups.

Variables	MAE (-) group (n=62)	MAE (+) group (n=43)	P value
Age (years)	61.42±11.59	66.07±11.21	**0.043**
Male, n (%)	30(48.4)	22 (51.2)	0.78
BMI (kg/m^2)	27.63±4.72	29.26±4.63	0.082
Diabetes, n (%)	24 (38.7)	22 (51.2)	0.206
Hyperlipidemia, n (%)	57 (91.9)	38 (88.4)	0.541
Active smoking, n (%)	21 (33.9)	13 (30.2)	0.695
Prior MI, n (%)	9 (14.5)	23 (53.5)	**<0.005**
Prior CABG, n (%)	9 (14.5)	8 (18.6)	0.576
Prior stroke, n (%)	2 (3.2)	12 (27.9)	**<0.005**
COPD, n (%)	3 (4.8)	11 (25.6)	**0.001**
AF, n (%)	4 (6.5)	4 (9.3)	0.588
Syntax score	3(0-10.75), n=56	8.5(3.5-18), n=36	**0.003**
Systolic BP (mmHg)	165 (150-180)	165 (160-180)	0.372
Diastolic BP (mmHg)	90 (83-105)	95 (85-100)	0.903
ACEI, n (%)	30 (48.4)	19 (44.2)	0.671
ARB, n (%)	17 (27.4)	15 (34.9)	0.414
Beta blocker, n (%)	48 (77,4)	34 (79.1)	0.841
CCB, n (%)	46 (74.2)	32 (74.4)	0.979
Alfa blocker, n (%)	12 (19.4)	7 (16.3)	0.687
Thiazide, n (%)	41 (66.1)	19 (44.2)	0.118
Furosemide, n (%)	6 (9.7)	8 (18.6)	0.186
MRA, n (%)	11 (17.7)	6 (14)	0.604
Statin, n (%)	45 (72.6)	31 (72.1)	0.956
Preprocedural total number of antihypertensives	3 (3-4)	3 (3-4)	0.092

Data are shown as mean±standard deiation or median (25th-75th) or n (%) where appropriate. ACEI=Angiotensin-coverting enzyme inhibitor, AF=Atrial fibrillation, ARB=Angiotensin receptor blocker, BP=Blood pressure, BMI=Body mass index, CABG=Coronary artery bypass grafting, CCB=Calcium channel blocker, COPD=Chronic obstructive pulmonary disease, MAE=Major adverse events, MRA=Mineralocorticoid receptor antagonist, SD=Standard deviation.

19 infection in 5 (17%), stroke in 3 (10%), major bleeding developing after the procedure in 1 (3.4%), acute kidney failure developing after the procedure in 1 (3.4%), abdominal aorta rupture in 1 (3.4%), pulmonary emboli in 1 (3.4%), intracranial hemorrhage in 1 (3.4%), chronic obstructive pulmonary disease (COPD) in 1 (3.4%), lung cancer in 1 (3.4%), and septic shock due to bacterial infection in 1 (3.4%). Of these 29 deaths, mortality was due to cardiovascular reasons in 12 (41.3%).

As 2 of the whole patient group were lost due to complications developing after the procedure, the mortality rate associated with the procedure was accepted as 1.9%. One-month mortality was seen in 3 (2.8%) patients, 6-month mortality in 5 (4.7%), 1-year mortality in 7 (6.6%), and mortality throughout the mean follow-up period (median 39 months) in 29 (27.6%).

Table 2. Comparison of laboratory, echocardiography and electrocardiography data

Variables	MAE (-) group (n=62)	MAE (+) group (n=43)	P value
Labaratory parameters			
Creatinine (mg/dL)	1.06 (0.87-1.50)	1.28 (0.99-1.91)	**0.040**
CrCl* (mL/min)	61.71 (42.75-87.36)	49.25 (32.73-74.19)	**0.014**
AST, (IU/L)	19 (14.75-24)	19 (14-22)	0.812
ALT, (IU/L)	15.5 (10.75-20)	15 (11-21)	0.881
Total cholesterol (mg/dL)	192.48±44.75	212.67±61.31	0.054
LDL (mg/dL)	114.78±37.51	133.82±48.88	**0.026**
HDL (mg/dL)	44.50 (39.70-53.62)	44 (37.90-48.48)	0.479
Non-HDL cholesterol (mg/dL)	114.86±45.12	168.14±58.52	**0.023**
Triglyceride (mg/dL)	132 (100.25-200)	159.37 (113-234)	0.078
HbA1c (%)	6.2 (5.5-7.12), n=54	6.44 (5.5-7.40), n=40	0.337
Uric acid (mg/dL)	6.32±1.93, n=47	6.59±1.93, n=35	0.534
Albumin (g/L)	41.12±4.65	38.66±8.31	0.082
Hemoglobin (g/dL)	12.78±1.90	12.58±1.78	0.588
White blood cell (× 10^3/mL)	8.65±2.56	9.01±2.51	0.482
Neutrophils (× 10^3/mL)	5.69±2.03	6.13±2.48	0.321
Lymphocytes (× 10^3/mL)	2.18±0.76	2.05±1	0.478
Platelet (×10^3/L)	267.79±89.94	255.34±71.47	0.451
RDW (fL)	14 (13.20-15.15)	14.1 (13.5-15.2)	0.483
MPV (fL)	10.38±1.73	9.5±1.48	**0.011**
PDW (fL)	16.25 (16-16.60)	16.40 (16-16.8)	0.112
TSH (mIU/L)	1.33 (0.78-2.31)	1.39 (0.94-3.17)	0.589
Echocardiography			
LVEDD (mm)	46 (46-50)	47 (45-50)	0.990
LAD (mm)	40 (35-42)	42 (38-45)	**0.005**
IVS (mm)	13.11±2.33	13.28±2.27	0.700
LVEF (%)	60 (59.5-65)	48 (44-60)	**<0.005**
PABs (mmHg)	31.69±9.58, n=55	34.86±7.81, n=37	0.098
Electrocardiography			
LVH by Socolow-Lyon index, n (%)	20 (32.3)	13 (30.2)	0.826

Data are shown as mean±standard deiation or median (25^{th}-75^{th}) or n (%) where appropriate. ALT=Alanine aminotransferase, AST=Aspartate aminotransferase, CrCl=Creatinine clearance, EF=Ejection fraction, HDL=High density lipoprotein, IVS=Interventricular septum, LAD=Left atrial diameter LDL=Low density lipoprotein, LVEDD=Left ventricular end-diastolic diameter, LVEF=Left ventricle ejection fraction, LVH=Left ventricular hypertrophy, MAE=Major adverse events, MPV=Mean platelet volume, PABs=Pulmoner artery systolic pressure, PDW=Platelet distribution width, RDW=Red cell distribution width, TSH=Thyroid-stimulating hormone, *Calculated with Modification of Diet in Renal Disease study.

The laboratory, TTE and ECG parameters of the patients are shown in Table 2, and the procedural and the post-procedural variables are shown in Table 3. The PTRS procedure was performed via the left radial artery in 2 (1.9%) patients. With the exception of 2 patients where >20% residual narrowness remained because of calcific renal arteries; the procedure was accepted as technically successful with a technical success rate of 98%. After the procedure, contrast nephropathy developed in 14 (13.3%) patients, which was treated with intravenous hydration, pseudoaneurysm in the femoral artery developed in 3 (2.9%), and femoral hematoma developed in 6 (5.7%), which recovered with medical treatment and rest. PTRS was determined to be beneficial in respect of blood pressure treatment in 81 (77.1%) patients.

Variables accepted as statistically significant as a result of the comparisons of the two groups were applied first with univariate then multivariate Cox regression analysis. The data of the Cox regression analyses are presented in Table 4.

In the Cox multivariate regression analysis, the LVEF, COPD, and number of antihypertensive drugs used after the procedure were determined to be independent predictors for MAE. ROC analysis was performed on the continuous variables of LVEF, and number of antihypertensive drugs after the procedure (Fig. 2). As a result of the ROC analysis, a cutoff value of ≤55% for LVEF was determined to have area under the curve (AUC) 0.733, 69.8% sensitivity, and 77.42% specificity (P<0.001). The use of more than 3 antihypertensive drugs after the procedure was found to have AUC 0.624, 34.88% sensitivity, and 82.26% specificity (P=0.023).

Table 3. Comparison of procedural and postprocedural data of MAE negative and positive groups.

Variables	MAE (-) group (n=62)	MAE (+) group (n=43)	P value
Procedural Data			
Solitary kidney, n (%)	2 (3.2)	2 (4.7)	0.543
Right renal artery, lesion degree (%)	80 (80-95), n=27	80 (80-95), n=24	0.108
Left renal artery, lesion degree (%)	80 (80-95), n=27	80 (80-95), n=13	0.930
Right PTRS, n (%)	27 (43.5)	25 (58.1)	0.141
Left PTRS, n (%)	27 (43.5)	13 (30.2)	0.167
Bilateral PTRS, n (%)	8 (12.9)	5 (11.6)	0.845
PTRA, n (%)	30 (48.4)	13 (30.2)	0.108
Bilateral renal artery stenting, n (%)	8 (12.9)	5 (11.6)	0.845
Total number of stents	1 (1-1)	1 (1-1)	0.397
Mean stent diameter (mm)	6 (5-7)	6 (5-6)	0.992
Mean stent length (mm)	15.5 (14-19)	15 (14-15)	0.063
Postprocedural Data			
Systolic BP (mmHg)	135 (130-148.75)	140 (135-170)	**0.016**
Diastolic BP (mmHg)	85 (80-85)	85 (80-100)	0.059
Full cure, n (%)	2 (3.2)	0	0.512
Beneficial for HT, n (%)	52 (83.9)	29 (67.4)	**0.049**
Contrast induced nephropathy, n (%)	6 (9.7)	11 (18.6)	0.186
Postprocedural total number of antihypertensives	2 (2-3)	3 (2-4)	**0.026**

Data are shown as median (25^{th}-75^{th}) or n (%) where appropriate. BP=Blood pressure, HT=Hypertension, MAE=Major adverse events, PTRA= Percutaneous transluminal renal angioplasty, PTRS=Percutaneous transluminal renal stenting.

Table 4. Univariate and multivariate cox regression analyses for determining independent predictors of MAE.

	Univariate Analysis			Multivariate Analysis		
Variables	**HR**	**95 % CI**	**P value**	**HR**	**95 % CI**	**P value**
Age	1.038	1-1.07	**0.017**	0.99	0.95-1.04	0.845
Prior MI	3.78	2.01-7.01	**<0.005**	1.34	0.55-3.30	0.514
Prior stroke	5.47	2.73-10.96	**<0.005**	1.92	0.66-5.59	0.229
COPD	4.09	2.01-8.32	**<0.005**	3.69	1.44-9.45	**0.006**
Postprocedural total number of antihypertensives	1.45	1.14-1.85	**0.002**	1.48	1-2.2	**0.049**
Beneficial for HT	0.34	0.17-0.66	**0.002**	1.17	0.42-3.24	0.755
Syntax score	1.039	1-1.07	**0.03**	1	0.95-1.06	0.727
CrCl	0.988	0.97-0.98	**0.04**	0.99	0.98-1.01	0.694
LDL	1.006	1-1.01	**0.016**	1.004	0.99-1.01	0.530
MPV	1.01	0.82-1.24	0.9			
LAD	1.08-	1.02-1.14	**0.006**	1.02	0.93-1.11	0.644
LV EF	0.95	0.93-0.98	**<0.005**	0.95	0.91-0.99	**0.042**
Postprocedural systolic BP	1	0.99-1.01	0.178			

BP=Blood pressure, COPD=Chronic obstructive pulmonary disease, CrCl=Creatinine Clearance, HT=Hypertension, LAD=Left atrial diameter, LDL=Low density lipoprotein, LVEF=Left ventricle ejection fraction, MAE=Major adverse events.

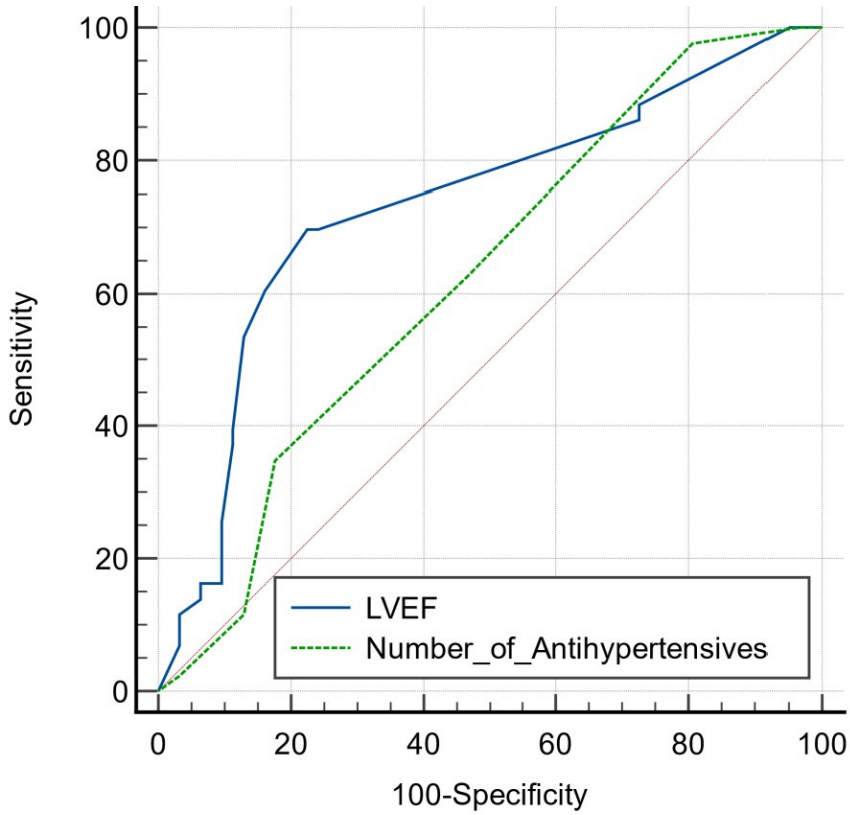

Fig. 2. ROC curve analysis for LV EF, and postprocedural total number of antihypertensives.

DISCUSSION

The aim of this study was to investigate adverse events and the predictors of these observed in patients who underwent a PTRS procedure because of ARAS. Although the SYNTAX score seemed to be significant in the univariate Cox regression analysis, it was not found to be an independent predictor. LVEF, COPD and the number of antihypertensive drugs used after the procedure were determined to be independent predictors for MAE.

In a previous study, the peri-procedural mortality rate was found to be 2.7%, which was close to the rate of the current study (1.9%). The mortality rate was determined to be 27.6% throughout the period of the current study (median 39 months), and when the mean follow-up period is taken into consideration, this rate was seen to be higher than the 24.2% (median 63 months) reported in the study by Wallace *et al*. [15]. However, the results obtained were seen to be similar to the 25.6% mortality rate of the ASTRAL study and the 24% mortality rate of the STAR study in literature [16, 17]. The median follow-up period (42 months) of the CORAL study [1] was very close to that of the current study, and the mortality rate of 13.7% was seen to be much lower than that of this and the above-mentioned studies [16, 17]. It was thought that the higher mortality rate in the current study compared to the CORAL [1] and Wallace *et al*. [15] studies could be attributed to the current study population having much more advanced atherosclerotic disease, especially compared with the CORAL study [1], and that this study was conducted during the COVID-19 pandemic. Another difference of the current study findings from the results of Wallace *et al*. [15] and the CORAL study [1] was that less than half (41.3%) of all the deaths were due to cardiovascular reasons.

In another study that was very similar to the current study in terms of design and results, age, COPD, heart failure, a history of treated subclavian artery stenosis, and advanced chronic renal failure were found to be independent predictors for mortality [18]. In the current study, COPD, LVEF, and the number of antihypertensive drugs after the procedure were determined to be independent predictors for MAE formed from combined end-points, rather than mortality. The current study results support the findings of the previous study in respect of COPD and heart failure. As COPD and ARAS share similar risk factors such as smoking, this may be related to the increased risk of adverse event. COPD has been proven to be an independent risk factor for mortality after coronary artery bypass grafting and percutaneous coronary intervention for CAD [19, 20]. Ledermen *et al*. [21] demonstrated that the risk of mortality increased with an increase in the severity of CAD in ARAS patients. However, it was interesting that in the current study results no independent association was seen between MAE and the SYNTAX score, which is a current score showing the severity of CAD.

It has been shown in previous studies that a history of MI, low LVEF and/or renal dysfunction are markers of poor prognosis in patients applied with renal arterial stent [7]. With the exception of LVEF, the other factors were not determined to be independent predictors in the current study. A low LVEF is known to be associated with increased mortality in many clinical conditions [22, 23]. However, there are limited data on the subject of the importance and cutoff value of LVEF in studies conducted on ARAS patients. The current study results showed that a cutoff value of ≤55 for LVEF was a significant predictor.

From a scan of the relevant literature, no evidence could be found that the total number of antihypertensive drugs used after the procedure could be a predictor of an adverse event. Therefore, the number of antihypertensive drugs after the procedure has been shown as a new predictor for this patient group. The fact of having to take more antihypertensive drugs after the procedure indicates that the patient has higher blood pressure values and has more difficulty in controlling this. A greater number of drugs may be associated with adverse events because of a more unwanted effect and greater drug interactions. This has been previously shown in studies of polypharmacy [24, 25]. This finding also demonstrates that blood pressure control is very important in these patients. Therefore, renal denervation could be considered in patients who cannot obtain blood pressure control despite a renal stenting procedure.

When the efficacy of the renal stent procedure was examined in respect of HT treatment, the procedure was found to be beneficial for 77.1% of the study group within the whole patient group. This rate was

close to the rate of 69.2% reported in a study by Dregoesc *et al*. [26]. The results of a meta-analysis showed that a stented or stentless PTRA procedure was not successful in respect of blood pressure control or improving renal functions in approximately 20-40% of patients [27]. The current study results were consistent with those of this meta-analysis.

Limitations

The main limitations of this study were that it was retrospective in design and was conducted with a limited number of patients in a single centre. Due to the retrospective nature of the study, there may not have been standardization in the TTE and PTRS procedures among different cardiologists as can be ensured in prospective studies. A further limitation could be said to be the lack of a control group treated conservatively.

CONCLUSION

The results of this study demonstrated that LVEF, the presence of COPD, and the total number of antihypertensive drugs used after the procedure were independent predictors for MAE seen after a PTRS procedure in ARAS patients. These predictors can be used to estimate the risk in these patients. To be able to prevent adverse events, it is important that patients with these markers are treated and followed up more closely. As these results were obtained from a limited number of patients there is a need for further, large-scale, multicentre studies to support these findings.

Ethical Statement

This study was approved by the Health Sciences University Bursa Yüksek Ihtisas Training and Research Hospital Medical Sciences Ethics Committee (Decision no: 2024-TBEK 2024/07/04 and date: 31.07.2024)

Authors' Contribution

Study Conception: FK, ÖFD; Study Design: FK; Supervision: FK; Funding: FK; Materials: FK; Data Collection and/or Processing: FK, ÖFD; Statistical Analysis and/or Data Interpretation: FK, ÖFD; Literature Review: FK, ÖFD; Manuscript Preparation: FK, ÖFD and Critical Review: FK, ÖFD.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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