Original paper

Clinical outcomes and effectiveness of renal artery stenting in patients with critical atherosclerotic renal artery stenosis: does it improve blood pressure control and renal function assessed by estimated glomerular filtration rate?

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Postep Kardiol Inter 2013; 9, 3 (33): 228–233
DOI: 10.5114/pwki.2013.37500

Abstract

Introduction: Atherosclerotic renal artery stenosis (ARAS) is associated with uncontrolled hypertension and chronic renal failure.

Aim: To evaluate the influence of gender and presence of chronic renal failure on the outcomes of percutaneous transluminal renal artery stenting (PTRAS) due to atherosclerosis.

Material and methods: A total of 28 ARAS patients underwent PTRAS and 36 stents were placed. Basal characteristics, laboratory data and blood pressure of patients were recorded. The differences between genders and improvement/deterioration of renal functions and blood pressure were analyzed. The predictors of outcomes were determined.

Results: Baseline characteristics were similar between men and women. Significant improvement of systolic and diastolic blood pressure control was achieved after PTRAS (153.04 ±17.07 mm Hg vs. 124.75 ±11.40 mm Hg, p = 0.001 and 92.50 ±10.76 mm Hg vs. 77.54 ±8.23 mm Hg, $p < 0.001$, respectively). Although mean estimated glomerular filtration rate (eGFR) and creatinine levels did not significantly improve at the 6-month follow-up visit compared to baseline values, of the 28 patients 13 (46.4%) patients had improvement of renal functions.

Conclusions: Our results suggest that PTRAS is a safe procedure and may offer blood pressure control but beneficial effects of PTRAS on renal function may be anticipated in a selected group of patients, especially those with a low eGFR.

Key words: renal artery stent, atherosclerosis, sex, chronic renal failure, hypertension.

Introduction

Nearly 90% of cases of renal artery stenosis (RAS) are associated with atherosclerosis and most commonly involve the origin and the proximal third of the main renal artery. Significant renal artery stenosis is present in up to 5% of hypertensive patients, 4–28% of patients with coronary artery disease undergoing coronary angiography and 40% of patients with peripheral artery disease [1, 2]. Atherosclerotic RAS is a progressive disease related to increased mortality and morbidity. However, the optimal treatment of atherosclerotic RAS is controversial. Percutaneous transluminal renal angioplasty with stent (PTRAS) is a safe, durable and effective procedure for the treatment of atherosclerotic RAS but the indications for PTRAS are disputed. The PTRAS is shown to be an effective method for the control of renovascular hypertension, but the success of PTRAS regarding maintenance of renal function in patients with normal or impaired renal function is still controversial [3–7]. The ASTRAL trial rekindled the debate about the effectiveness of PTRAS [3]. The trial enrolled 806 ran-

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Received: 12.02.2013, **accepted:** 31.05.2013.

domly assigned patients (403 patients in the PTRAS group and 403 patients in the medical therapy group) from 2000 to 2007 to be followed over a 5-year period. Although the baseline characteristics appeared similar, nearly one-half of the patients in both groups had ARAS < 70%, which created a significant bias against PTRAS. Objective validation of the stenosis degree was also lacking in this study, resulting in overestimation of narrowing. The ASTRAL investigators failed to recognize or acknowledge that there is no clinical equipoise in randomizing mild ARAS lesions to revascularization. Furthermore, the procedural success rate was lower with a high rate of complications. Therefore, the results of the ASTRAL trial study should be carefully evaluated.

Aim

The aim of the present study is to evaluate the influence of gender and presence of chronic renal failure on the outcomes of renal artery stenting due to atherosclerosis.

Material and methods

Study population

One hundred thirty-seven consecutive patients with resistant hypertension (needing at least 3 medications including diuretics and other antihypertensive drugs such as angiotensin receptor blockers, angiotensin-converting-enzyme inhibitors, nitrates, α-blockers, β-blockers and calcium channel blockers) and suspected coronary artery disease underwent diagnostic renal angiography along with coronary angiography due to suspected coronary artery disease. Severe atherosclerotic RAS was defined as luminal narrowing ≥ 70% by renal angiography. Of the 137 patients, severe RAS was detected in 28 patients and treated with PTRAS. These 28 patients were included in this study. Of these 28 patients critical coronary stenosis was detected in 18 patients and these 18 patients were treated with coronary stents. The remaining 10 patients had non-critical stenosis of coronary arteries. Informed consent was obtained from all subjects, and the investigation conforms to the principles outlined in the Declaration of Helsinki. Coronary artery disease risk factors, blood pressures, anti-hypertensive medications, and laboratory and echocardiographic data were recorded.

Definitions

Unilateral stenosis was defined as unilateral ostial stenosis with no stenosis in the contralateral artery. Bilateral stenosis was defined as ostial stenosis on both sides, unilateral ostial stenosis with contralateral occlusion, or solitary kidney with ostial stenosis. For each patient, coronary artery disease risk factors including diabetes mellitus, smoking and hypercholesterolemia were obtained. Diabetes mellitus was defined as fasting blood glucose > 126 mg/dl or patients on oral antidiabetic and/or insulin therapy. Hyperlipidemia is accepted as fasting low-density lipoprotein (LDL) cholesterol level > 160 mg/dl or patients on antihyperlipidemia therapy.

Blood pressure measurements

The blood pressure was measured using a mercury sphygmomanometer with a cuff appropriate to the arm circumference (Korotkoff phase I for systolic blood pressure and V for diastolic blood pressure). Blood pressure measurements were performed twice for each subject in outpatient clinical settings at least 30 min after resting in compliance with the World Health Organization recommendations and their mean was used for statistical analysis.

Laboratory measurements

The laboratory data including blood cell counts, fasting glucose, total cholesterol, LDL, high-density lipoprotein (HDL), urea and creatinine were obtained before coronary angiography. Serum creatinine levels were assessed 6 months after the procedure, again. Estimated glomerular filtration rate (eGFR) was calculated using the Cockcroft-Gault formula [8]. Chronic renal failure was defined as eGFR < 60 ml/min/1.73 m^2.

Transthoracic echocardiographic assessment such as ejection fraction % (EF%) was performed in all patients. Renal atrophy was assessed by renal ultrasonography.

Percutaneous technique

Renal artery stenting was performed at least one month after coronary angiography and/or percutaneous coronary intervention (range: 1–2 months). Femoral arterial puncture was performed in all patients, and all procedures were performed through a 7 F sheath introducer, with right Judkins or internal mammary artery guiding catheter via a 0.14 mm coronary guide wire. The guide wire was passed through the stenosis and a balloon-expandable bare metal stent was placed over the guide wire. For treatment of ostial stenoses, the stent was positioned so that 1 mm to 2 mm protruded into the aortic lumen, ensuring complete coverage of the aortic plaque. An intervention was considered technically successful if the residual stenosis was < 30%. Procedural success is defined as the presence of technical success without major complications. Antiplatelet therapy was started at least 1 day before intervention and routinely consisted of 75 mg of clopidogrel daily for 3 months and 100 mg of aspirin indefinitely. Immediately before the intervention, we administered a bolus dose of 5000 IU of heparin. After the procedure the mainstay of the antihypertensive therapy included β-blockers with angiotensin-converting-enzyme inhibitors/angiotensin receptor blockers. In patients with congestive symptoms or blood pressure beyond the targets, diuretics were added.

Statistical analysis

Statistical analyses were performed using SPSS version 17.0 for Windows software (SPSS Inc., Chicago, USA). Continuous variables are expressed as mean ± standard deviation (SD) and categorical variables are expressed as percentage. Comparisons of continuous variables were performed using the unpaired Student *t* test, the paired Student *t* test for normally distributed variables, and the Wilcoxon test was used for the analysis of non-normally distributed variables. Categorical variables were compared with the χ^2 test. Results were evaluated within the 95% confidence interval and $p < 0.05$ was accepted as significant.

Results

A total of 28 atherosclerotic RAS patients underwent percutaneous transluminal renal angioplasty and 36 renal stents were placed. Procedural success was achieved in all patients (100%). Of the 28 patients, left renal artery stenosis was found in 10 patients (35.7%), right renal artery stenosis in 10 (35.7%), and bilateral renal artery stenosis in 8 (28.6%). Major complications including procedure-related death, cerebrovascular accident, myocardial infarction, arterial rupture, embolism, and acute renal failure were not observed. Two patients had hematoma at the puncture site. The mean duration of hypertension was 17.71 ±11.49 years. Angiotensin-converting-enzyme inhibitors were used by 17.9%, angiotensin receptor blockers by 42.9%, β-blockers by 75.0%, calcium channel blockers by 67.9%, α-blockers by 14.3%, nitrates by 39.3%, centrally acting antihypertensives by 14.3% and diuretics by 100% of patients. None of the patients with bilateral ARAS used angiotensin-converting-enzyme inhibitors or angiotensin receptor blockers. Baseline characteristics including age, presence of diabetes, hyperlipidemia, smoking habit, medications, location of stenosis, stent size and laboratory data were similar between men and women (Table 1). Basal systolic blood pressure levels were similar between men and women but diastolic blood pressure levels were significantly higher among women ($p = 0.014$). Post-PTRAS systolic and diastolic blood pressure levels were similar between men and women. Significant improvement of systolic and diastolic blood pressure control was achieved after PTRAS (153.04 ±17.07 mm Hg vs. 124.75 ±11.40 mm Hg, $p = 0.001$ and 92.50 ±10.76 mm Hg vs. 77.54 ±8.23 mm Hg, $p < 0.001$, respectively) (Figure 1). Both men and women showed similar benefit from PTRAS for systolic and diastolic blood pressure regulation (Table 2). Baseline and post-PTRAS creatinine levels were similar for men and women. While basal eGFR was similar between men and women, post-PTRAS eGFR levels were significantly higher in males ($p = 0.034$). Although mean eGFR and creatinine levels did not significantly improve at the 6-month follow-up visit com-

Table 1. Baseline characteristics of patients

Variable	Men (*n* = 13)	Women (*n* = 15)	Total (*n* = 28)	Value of *p*
Age [years]	58.77 ±14.12	67.87 ±14.37	63.64 ±14.73	0.104
DM, *n* (%)	4 (30.8)	4 (26.7)	8 (28.6)	1.000
HL, *n* (%)	6 (46.2)	4 (26.7)	10 (35.7)	0.283
Smoking, *n* (%)	6 (46.2)	2 (13.3)	8 (28.6)	0.096
PreDN	3.85 ±0.80	3.60 ±0.91	3.71 ±0.85	0.458
PostDN	2.31 ±0.75	2.60 ±0.63	2.46 ±0.69	0.274
DL, *n* (%)	11 (84.6)	13 (86.7)	24 (85.7)	0.877
EF [%]	62.31 ±4.84	61.00 ±4.71	61.61 ±4.72	0.476
SL [mm]	17.27 ±2.19	16.69 ±2.84	16.97 ±2.32	0.551
SD [mm]	6.20 ±0.56	6.00 ±0.82	6.08 ±0.74	0.452
CAD, *n* (%)	9 (69.2)	11 (73.3)	20 (71.4)	0.811
PAH, *n* (%)	2 (15.4)	1 (6.7)	3 (10.7)	0.583
RA, *n* (%)	2 (15.4)	4 (26.7)	6 (21.4)	0.655
WBC	9.09 ±2.43	8.01 ±3.05	8.51 ±2.78	0.313
Hemoglobin	11.91 ±1.68	11.62 ±1.75	11.75 ±1.69	0.662
Ure	49.46 ±20.22	48.06 ±26.58	48.71 ±23.42	0.878
CRF, *n* (%)	7 (53.8)	9 (60.0)	16 (57.1)	0.743
IeGFR, *n* (%)	6 (46.2)	7 (46.7)	13 (46.4)	0.978
Total C	186.31 ±46.25	205.47 ±46.62	196.57 ±40.61	0.286
LDL	120.08 ±38.99	131.13 ±42.75	126.00 ±40.68	0.484
HDL	37.02 ±10.33	46.22 ±12.68	41.95 ±12.36	0.047

DM – diabetes mellitus, HL – hyperlipidemia, PreDN – preprocedural drug number, PostDN – postprocedural drug number, DL – medication dosage lowering, EF – left ventricle ejection fraction, SL – stent length, SD – stent diameter, CAD – significant coronary artery disease, PAH – peripheral artery disease, RA – renal atrophy, WBC – white blood cell count, CRF – chronic renal failure, IeGFR – improved estimated glomerular filtration rate, Total C – total cholesterol, LDL – low-density lipoprotein, HDL – high-density lipoprotein

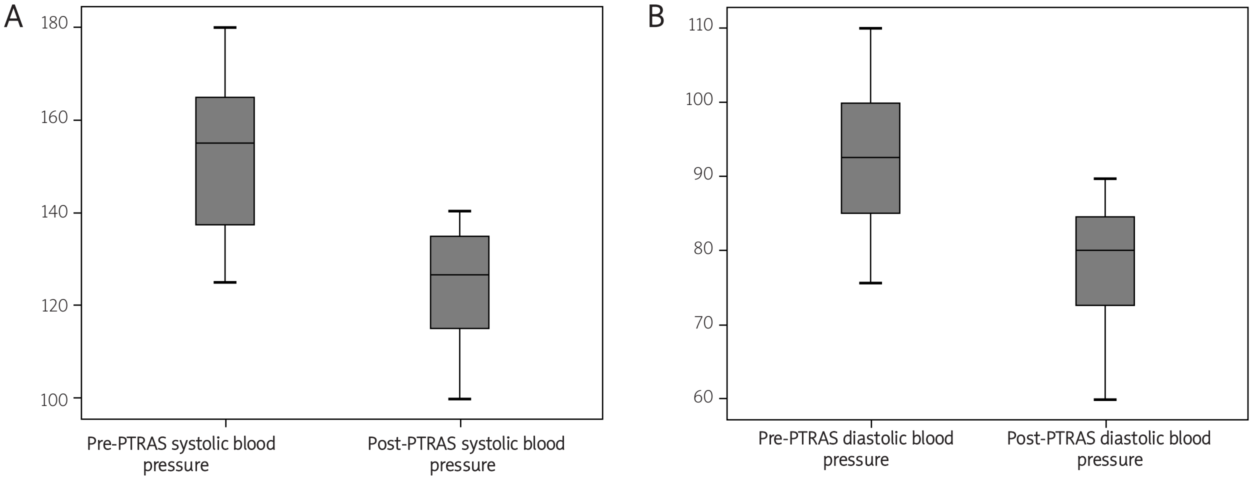

Fig. 1. Box plot graph shows pre- and post-PTRAS values of systolic blood pressure (**A**) and diastolic blood pressure (**B**)

Table 2. Pre-percutaneous transluminal renal angioplasty with stent (PTRAS) and at 6-month follow-up results of blood pressure, medications, creatinine and estimated glomerular filtration rate

Variable	Pre-PTRAS	Post-PTRAS	Value of *p*
SP	153.04 ±17.07	124.75 ±11.40	< 0.001
Men	146.92 ±15.88	124.08 ±9.00	< 0.001
Women	158.33 ±16.76	125.33 ±13.43	< 0.001
DP	92.50 ±10.76	77.54 ±8.23	< 0.001
Men	87.31 ±8.81	76.31 ±7.93	0.001
Women	97.00 ±10.49	78.60 ±8.60	< 0.001
Number of drugs	3.71 ±0.85	2.46 ±0.69	< 0.001
Men	3.85 ±0.80	2.31 ±0.75	< 0.001
Women	3.60 ±0.91	2.60 ±0.63	0.006
Creatinine	1.13 ±0.31	1.13 ±0.31	0.150
Men	1.41 ±0.53	1.17 ±0.32	0.088
Women	1.15 ±0.42	1.10 ±0.30	0.767
eGFR	60.89 ±35.21	61.75 ±21.08	0.899
Men	62.77 ±31.31	70.69 ±22.94	0.300
Women	59.27 ±39.30	54.00 ±16.37	0.632

PTRAS – percutaneous transluminal renal artery stenting, SP – systolic blood pressure, DP – diastolic blood pressure, eGFR – estimated glomerular filtration rate

pared to baseline values, of 28 patients 13 (46.4%) patients had improvement of renal functions (Figure 2). Among patients with improved eGFR, basal eGFR was significantly lower, basal creatinine was significantly higher and hyperlipidemia and chronic renal failure were significantly more common compared to non-responders (Table 3).

Discussion

We found that blood pressure was significantly improved and medication needed to control blood pressure was significantly decreased after PTRAS. Although renal functions including eGFR and creatinine levels were not significantly affected by PTRAS, 46.4% of patients showed improvement of eGFR. Among patients with improved eGFR, baseline creatinine levels were significantly higher while basal eGFR levels were significantly lower. Presence of chronic renal failure was more common in these patients too. Data gathered from this subgroup suggested that patients with chronic renal failure had the most advantageous clinical outcomes from PTRAS. Both genders were shown to be equally affected by PTRAS.

Renal artery stenosis is an important cause of renovascular hypertension and renal insufficiency [9]. Cardiovascular mortality and morbidity are increased in patients with atherosclerotic RAS that affects both genders [10, 11].

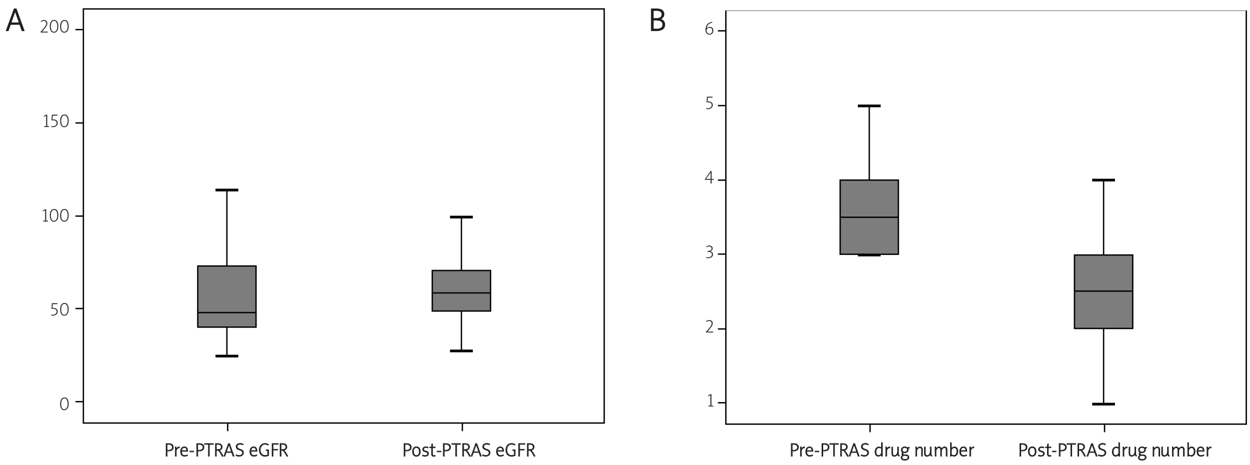

Fig. 2. Box plot graph shows pre- and post-PTRAS values of eGFR (**A**), antihypertensive drug number needed to control blood pressure (**B**)

Table 3. Characteristics of patients with increased and decreased estimated glomerular filtration rate

Variable	IeGFR (*n* = 13)	DeGFR (*n* = 15)	Value of *p*
Pre-DN	3.77 ±0.93	3.67 ±0.82	0.758
Post-DN	2.54 ±0.78	2.40 ±0.63	0.607
SP	147.69 ±14.52	157.67 ±18.21	0.125
DP	89.62 ±9.23	95.00 ±11.65	0.192
EF	60.92 ±4.77	62.20 ±4.77	0.486
WBC	8.98 ±2.96	8.10 ±2.66	0.415
HB	11.10 ±1.54	12.32 ±1.66	0.055
eGFR1	36.77 ±7.70	81.80 ±36.49	< 0.001
Creatinine	1.66 ±0.35	0.92 ±0.26	< 0.001
LDL	137.54 ±39.13	116.00 ±40.69	0.166
HDL	46.15 ±10.52	38.3 ±12.99	0.094
TC	210.23 ±47.50	184.73 ±43.95	0.152
DM	4 (30.8%)	4 (26.7%)	0.811
HL	9 (69.2%)	1 (6.7%)	0.001
CAD	8 (61.5%)	12 (80.0%)	0.410
PAH	2 (15.4%)	1 (6.7%)	0.583
Renal atrophy	5 (38.5%)	1 (6.7%)	0.069
CRF	13 (100%)	3 (20.0%)	< 0.001

IeGFR – improved glomerular filtration rate, DeGFR – decreased glomerular filtration rate, Pre-DN – preprocedural drug number used, Post-DN – postprocedural drug number used, SP – systolic blood pressure, DP – diastolic blood pressure, EF – left ventricle ejection fraction, WBC – white blood cell count, HB – hemoglobin, eGFR – estimated glomerular filtration rate, LDL – low-density lipoprotein, HDL – high-density lipoprotein, TC – total cholesterol, DM – diabetes mellitus, HL – hyperlipidemia, CAD – coronary artery disease, PAH – peripheral artery disease, CRF – chronic renal failure

In accordance with the literature, the numbers of male and female patients were approximately equal in our study. Atherosclerotic RAS usually affects the renal artery ostium, thus complicating this procedure. Although PTRAS is effective in the treatment of RAS, optimal management of RAS is still controversial. The European Society of Cardiology guidelines on the diagnosis and treatment of peripheral arterial disease suggested PTRAS as a class 2B indication in patients with symptomatic severe ARAS (> 60% renal artery stenosis) or impaired renal functions or recurrent unexplained congestive heart failure or pulmonary edema with preserved ejection fraction [12]. Studies showed that the percutaneous procedure had little advantage or no clear effect on progression of impaired renal function [3, 4, 13]. However, contrary to the literature, critical stenosis is accepted as > 50% luminal narrowing in these studies. Furthermore, the procedural success rates were lower and complication rates were higher in these studies too. In contrast to these studies, critical stenosis was defined as luminal narrowing > 70% in our study and we achieved a 100% angiographic success rate without major complications. Zeller *et al.* [14] studied the long-term impact of stent-supported angioplasty on renal function and blood pressure control in 456 hemodynamically significant de novo RAS cases. They found that stent-supported angioplasty of RAS preserves renal function and improves blood pressure control in a broader spectrum of patients. Also, Lederman *et al.* [15] studied the technical and clinical success of renal artery stenting in 300 consecutive patients with hypertension or renal insufficiency. They showed that 70% of patients had improved blood pressure control regardless of renal function after a median follow-up of 16 months. Similar to these findings, we observed that patients substantially benefited from the PTRAS procedure.

Measuring serum creatinine is a useful and sensitive marker of evaluating renal dysfunction. Creatinine is a non-protein waste product of creatine phosphate metabolism by skeletal muscle. Its production is continuous and is proportional to muscle mass. Creatinine is freely filtered and therefore the serum creatinine level depends on the GFR. Previous studies have shown serum creatinine levels significantly decreased after PTRAS and the decrease in serum creatinine levels tends to be larger in patients with higher serum creatinine levels [14]. Although a significant decrease of mean serum creatinine levels was not observed in our study, we found that 46.4% of patients had improvement of eGFR after PTRAS and among these patients the baseline eGFR rate was significantly lower. This finding may be associated with correction of decreased blood flow in the ischemic renal area [16]. Moreover, patients with chronic renal failure had a limited number of functioning nephrons and decreased blood flow further deteriorates the glomerular filtration. Correction of blood flow may provide enough perfusion pressure, and thus improvement of renal functions.

This study has several limitations. Blood pressure recordings were performed in outpatient clinic settings. Measurement of ambulatory blood pressure may supply beneficial information. The follow-up period was relatively short. The atheroembolization may deteriorate renal function during PTRAS [17, 18], but unfortunately we did not perform the procedure under distal protection. Renal artery stenosis is determined anatomically by angiographic appearance in this study. Doppler flow studies may give additional information regarding the severity of stenosis but unfortunately a Doppler flow study was not performed in this study. Another limitation of our study was the relatively small patient population; thus large scale studies with prolonged follow-up are further required to confirm our findings.

Conclusions

Our results suggest that renal artery stenting is a safe procedure and may offer blood pressure control but beneficial effects of PTRAS on renal function may be anticipated in a selected group of patients, especially those with a low eGFR and bilateral RAS.

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