Efficiency of Percutaneous Stent Angioplasty in Renal Artery Stenosis – 15 Years of Experience at a Single Center

Effizienz der perkutanen Stentangioplastie bei Nierenarterienstenose – die 15-jährige Erfahrung eines Einzelzentrums

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ZUSAMMENFASSUNG

Hintergrund Bestimmung der therapeutischen Effizienz der perkutanen Revaskularisation bei Nierenarterienstenose (RAS) sowie der Rolle umfassender Faktoren wie Patientenauswahl und Grad der Arterienstenose für das klinische Ergebnis.

Methode Bei 101 Patienten mit hämodynamisch relevanter RAS wurde eine perkutane Angioplastie (PTA) durchgeführt. 65,7 % waren männlich, das Durchschnittsalter betrug 64 Jahre (Bereich: 18–84). Die klinischen Daten wurden retrospektiv analysiert. Serumkreatinin (Cr), glomeruläre Filtrationsrate (GFR) und Blutdruckwerte (BP) prä- und postinterventionell sowie zwischen 6 Monaten und einem Jahr wurden retrospektiv erhoben und statistisch analysiert.

Ergebnisse Follow-up-Daten waren bei 34 (33,7 %) und 28 Patienten (27,7 %) jeweils für Cr und BP verfügbar. Bei der Nachuntersuchung wurde ein signifikanter Abfall des mittleren arteriellen Drucks (MAP) beobachtet (Mittelwert –5,27 mmHg). Höhere Cr- und MAP-Basiswerte zeigten einen ausgeprägteren Abfall im Follow-up (Cr: p = 0,002; Differenz zum Basiswert –0,25 mg/dl, 95 %-KI –0,36 bis-0,07 und BP p < 0,001; Differenz zum Basiswert –0,72mmHg; 95 %-KI –1,4 bis –0,40). Es bestand kein Zusammenhang zwischen Komorbiditäten, Geschlecht und Stenosegrad mit dem Nieren- und Blutdruckergebnis. Beim Follow-up wurde keine signifikante Verbesserung der Nierenfunktion beobachtet (mittlerer Cr-Abfall: –0,015 mg/dl). In der Altersgruppe 51–60 Jahre zeigte sich eine signifikante Verbesserung des Blutdrucks (p = 0,030; Differenz zum Ausgangswert –19,2mmHg; 95 %-KI –34 bis –4,3). Die antihypertensive Medikation nach der Angioplastie wurde leicht reduziert (0,2 weniger). Unbedeutende Komplikationen wurden bei 5 Eingriffen festgestellt (4,9 %).

Schlussfolgerung Die perkutane Nierenarterienrevaskularisierung bei vorliegender atherosklerotischer RAS ist ein sicheres Verfahren, das mit einem signifikanten Abfall des postprozeduralen Blutdrucks einhergeht. Eine signifikante Verbesserung der Nierenfunktion wurde nicht beobachtet. Weitere prospektive Studien zur Patientenauswahl sind notwendig.

Kernaussagen:

- Die perkutane Stentangioplastie bei Nierenarterienstenose ist mit einer signifikanten Verbesserung der postprozeduralen Blutdruckkontrolle verbunden.
- Es gab keine Verbesserung der Nierenfunktion nach der perkutanen Stentangioplastie bei Nierenarterienstenose (RAS).
- Die perkutane Stentangioplastie ist ein sicheres Verfahren.

ABSTRACT

Purpose To determine the therapeutic efficiency of percutaneous revascularization in renal artery stenosis (RAS), as well as the role of comprehensive factors such as patient selection and degree of artery stenosis, on clinical outcome.

Methods and Materials 101 patients with hemodynamically relevant RAS underwent percutaneous angioplasty (PTA). 65.7 % were male (mean age: 64 years; range: 18–84). The clinical data was retrospectively analyzed. The serum creatinine (Cr), glomerular filtration rate (GFR), and blood pressure (BP) levels pre- and postprocedural, between 6 months and 1 year, were retrospectively collected and statistically analyzed.

Results Follow-up data was available in 34 (33.7 %) and 28 patients (27.7 %) for Cr and MAP, respectively. A significant drop in mean arterial pressure (MAP) was observed on follow-up (mean −5.27 mmHg). Higher baseline Cr and MAP values showed a more pronounced drop in the follow-up (Cr: p 0.002; difference to baseline −0.25 mg/dL, 95 %CI:−0.36, −0.07 and BP p < 0.001; diff. to baseline −0.72 mmHg; 95 %CI: −1.4, −0.40). There was no association between comorbidities, gender, and degree of stenosis with renal and BP outcome. No significant improvement in renal function was observed on follow-up (mean Cr drop: −0.015 mg/dL). The age group 51–60 years showed a significant improvement in BP (p 0.030; diff. to baseline −19.2 mmHg; 95 %CI: −34, −4.3). There was a slight reduction in antihypertensive medication following angioplasty (0.2 fewer). Minor complications were recorded in five procedures (4.9 %).

Conclusion Percutaneous renal artery revascularization in the presence of atherosclerotic RAS is a safe procedure associated with a significant drop in post-procedural BP. No significant improvement in renal function was observed. Further prospective studies focused on patient selection are necessary.

Key Points:

- Percutaneous stent angioplasty in renal artery stenosis is associated with a significant improvement in post-procedural blood pressure control.
- There is no improvement in renal function after percutaneous stent angioplasty for renal artery stenosis (RAS).
- Percutaneous stent angioplasty is a safe procedure.

Citation Format

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Introduction

Renal artery stenosis (RAS) is believed to be present in 1 % to 5 % of patients with hypertension [1]. Furthermore, the prevalence in elderly patients has been reported to be as high as 7 % [2]. The great majority of cases are associated with atherosclerotic disease [3]. Fibromuscular dysplasia accounts for 10 % to 30 % of cases of renovascular hypertension and is referred to as its most common cause in young adults and children [4]. Other causes for secondary renovascular hypertension include vasculitis and embolic disease.

RAS is associated with progressive ischemic nephropathy, hypertension, left ventricular hypertrophy, congestive heart failure, and pulmonary edema, also known as Pickering syndrome [5]. The diagnosis is made by duplex ultrasound, renal arteriography, magnetic resonance angiography, or computed tomography angiography [1]. Therapeutic options include surgical vascular repair, medical therapy by means of blood pressure control and statins, as well as percutaneous angioplasty (PTA). In the 1990 s, with the development of percutaneous angioplasty, percutaneous renal artery revascularization became the established standard in the treatment of relevant stenosis and the number of procedures increased significantly [6]. The largest randomized trials so far, Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis (CORAL) [7] and Angioplasty and Stenting for Renal Artery Lesions (ASTRAL) [8], failed to show any benefit of revascularization over medical therapy. However, both trials presented fundamental flaws in their study design: patients enrolled in ASTRAL were minimally symptomatic or presented subclinical, likely non-obstructive renal artery lesions. Ca. 50 % of the patients enrolled in CORAL had no clinically significant renal failure and one third were diabetic [9, 10]. Saad et al. reported that the revascularization, despite restoring blood flow and reducing tissue hypoxia, failed to reduce the markers of chronic inflammation responsible for tissue injury [11]. The results from previous retrospective as well as randomized trials have been heterogeneous. This has led to a sustained ambiguity and uncertainty in the management of patients with RAS.

In our university medical center we performed a total of 128 revascularization procedures during a period from 2000 to 2015.

The aim of this study was to analyze the clinical outcome of patients who underwent renal stent angioplasty and to look for further insights into patient selection and the role of PTA in reducing renal injury and hypertension. The presence of concomitant diseases and their effect on the outcome should be assessed.

Materials and Methods

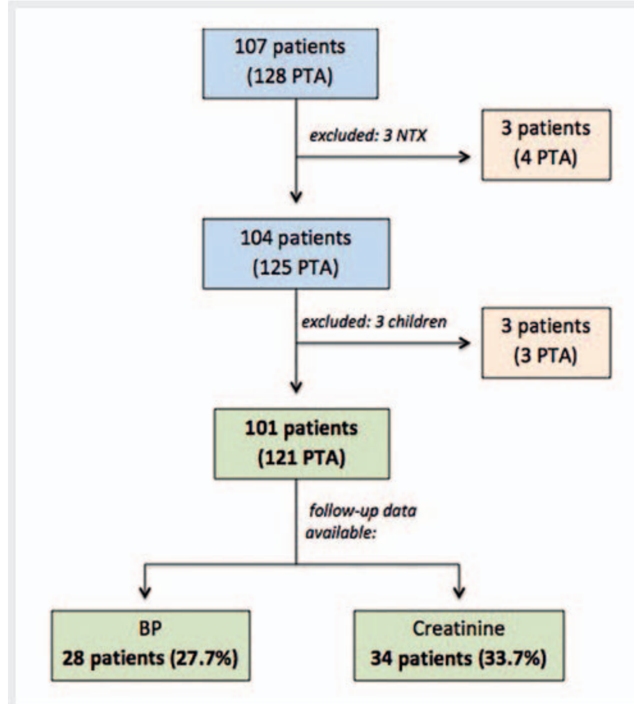
This retrospective study was HIPAA compliant and was approved by our institutional review board, which waived the need for informed consent. This retrospective case-control study aimed to analyze the data of all percutaneous renal artery angioplasty interventions performed at our university medical center between 2000–2015. The inclusion criteria were: a) presence of an atherosclerotic stenosis > 50 %; b) angioplasty with placement of a stent. The exclusion criteria were: a) ineligibility for PTA; b) insufficient pre-procedural clinical information.

The clinical data were extracted from the internal patient medical records and, when possible, primary care clinics were contacted in order to gain follow-up information. Age, gender, concomitant diseases, technical aspects of the procedure, creatinine, and blood pressure values pre- and post-procedural (time interval: 6 months to 1 year), complications as well as medical therapy before and after the procedure were extracted and statistically analyzed. The GFR was calculated for each patient using the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation [12].

A total of 128 percutaneous renal artery angiographies were performed in 107 patients (▶ **Fig. 1**). Children (n = 3) and patients with a transplanted kidney were excluded (n = 3). 10 procedures were repeated due to in-stent-stenosis (8.2 %), in two patients PTA was performed in two different accessory arteries (1.7 %). In eight patients the procedure was repeated on the contralateral side (6.6 %). All procedures were performed by two experienced interventional radiologists with more than 15 years of experience in interventional radiology.

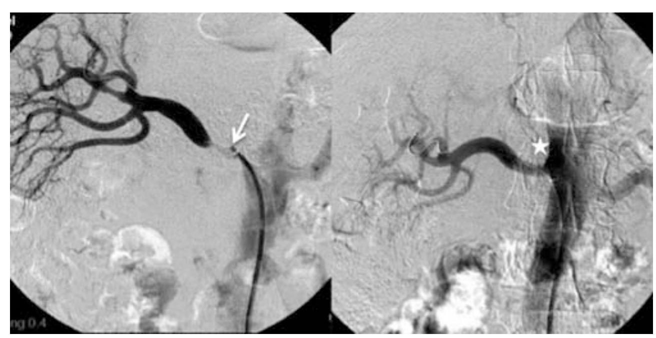
Patients with clinical suspicion of RAS were evaluated by an expert team of nephrologists and interventional radiologists. The preprocedural workup included renal Doppler ultrasound, blood tests, and in some cases MRI renal angiography. All patients signed an informed consent form. All procedures were performed under conscious sedation and local anesthesia. After puncture of the femoral artery, an Arrowflex 5F-introducer sheath (Teleflex, Wayne, PA, USA) was placed in the infrarenal abdominal aorta. A 5F pigtail catheter (Cordis, Fremont, CA, USA) was introduced over a 0.035-inch guide-wire (Terumo, Tokyo, Japan) under fluoroscopic guidance into the suprarenal abdominal aorta and an abdominal angiography using iodinated contrast medium (Imeron, Bracco, Milan, Italy) was performed in all patients to confirm stenosis. Removal of the pigtail catheter and placement of a 5- or 4-F Cobra 2 or Sidewinder-1 main catheter (Terumo, Tokyo, Japan) into the ostium of the stenotic renal artery was performed. After intraarterial injection of 2500 units of heparin, the stenosis was passed and the main catheter was conducted into the post-stenotic part of the main renal artery. After that, a 0.014-inch Spartacore guide-wire (Abbott, Chicago, IL, USA) was advanced through the main catheter, followed by angioplasty using a balloon mounted Herkulink-Stent (Abbott, Chicago, IL, USA) under fluoroscopic guidance. Postprocedural 2500 units of heparin were injected intraarterially. Renal angiography was repeated at the end of the procedure to evaluate therapeutic success (▶ **Fig. 2**).

The majority of patients were male (65.7 %) and the mean age was 64 years (range: 18–84) (▶ **Table 1**). Femoral artery access was used in most cases (n = 119, 93 %). In 3 instances a transbrachial approach was used (2.5 %). The right renal artery had the highest number of procedures (52.3 %). The degree of stenosis was determined visually by the operating interventionalist, with moderate corresponding to stenosis of 50–70 % (14.9 % of cases), severe 70–90 % (63.4 %) and extremely severe above 90 % (21.8 %). 9 patients had a solitary kidney (8.9 %) and in 17 patients kidney atrophy could be seen (16.8 %). In 7 patients the revascularization procedure was performed in an atrophic kidney (6.9 %). Concomitant diseases included ischemic heart disease (n = 34, 33.7 %), cerebrovascular disease (n = 26, 25.7 %), atherosclerosis (n = 27, 26.7 %) and type II diabetes (n = 19, 18.8 %). Chronic hypertension and renal insufficiency were often associated with RAS (99 % and 42.8 %, respectively). In 5 patients (4.9 %) a dissection of the kidney artery could be observed immediately after dilation, 3 of which required stent insertion. There were no major complications such as bleeding, kidney loss, or death. Following the intervention, 300 mg as an oral bolus and 75 mg of clopidogrel for 1 month, and a lifelong 100 mg daily dose of acetylsalicylic acid were prescribed to all patients.



▶ **Fig. 1** STARD diagram of the study population with available follow-up data. Children and patients with transplanted kidneys (NTX) were excluded from the study.

▶ **Abb. 1** STARD-Diagramm der Studienpopulation mit verfügbaren Follow-up-Daten. Kinder und Patienten mit transplantierten Nieren (NTX) wurden aus der Studie ausgeschlossen.



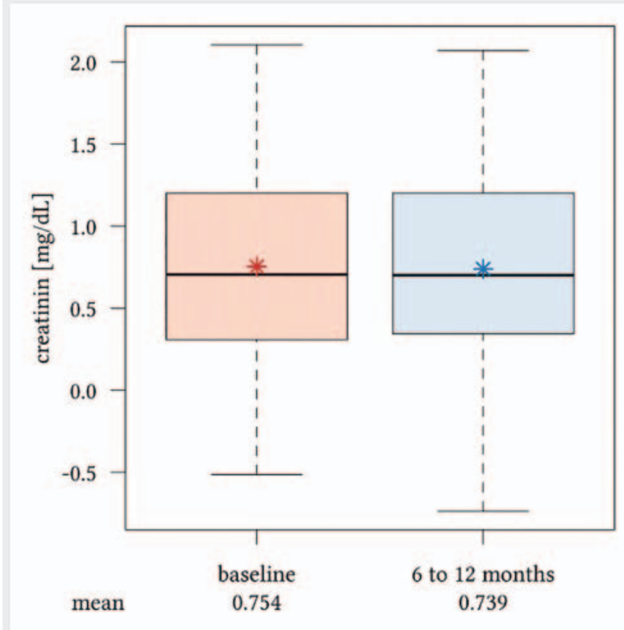
▶ **Fig. 2** DSA image showing severe proximal stenosis of the right renal artery before (arrow) and after angioplasty (star).

▶ **Abb. 2** DSA-Bild mit Nachweis schwerer proximaler Stenose der rechten Nierenarterie vor (Pfeil) und nach Angioplastie (Stern).

▶ **Table 1** Baseline characteristics of patients who underwent renal stent angioplasty between 2000 and 2015.

▶ **Tab. 1** Ausgangsdaten der renalen Stentangioplastien zwischen 2000 und 2015.

male gender (n/%)	69 (65.7)
age range	
▪ < 50 yrs	14/13.8
▪ 51–60 yrs	21/20.8
▪ 61–70 yrs	34/33.7
▪ > 70 yrs	32/31.7
PTA (n/%)	
▪ right	59/48.8
▪ left	54/44.6
▪ bilateral	8/6.6
degree of stenosis (n/%)	
▪ moderate (< 70 %)	15/14.8
▪ severe (70–90 %)	64/63.4
▪ extremely severe (> 90 %)	22/21.8
solitary kidney (n/%)	9/8.9
renal atrophy (n/%)	
▪ ipsilateral	7/6.9
▪ contralateral	9/8.9
▪ bilateral	1/0.99



▶ **Fig. 3** Boxplot showing an insignificant drop in creatinine values 6–12 months after stent angioplasty (mean −0.015 mg/dL).

▶ **Abb. 3** Der Boxplot zeigt einen nicht signifikanten Abfall der Kreatininwerte 6–12 Monate nach der Stentangioplastie (Mittelwert −0,015 mg/dL).

Statistical analysis

Concomitant diseases were divided into 5 categories for statistical purposes: vascular (arteritis and fibrous dysplasia); cardiovascular (atherosclerosis and coronary artery disease); lifestyle (obesity, smoking, diabetes mellitus type II); cardiac (heart insufficiency und left ventricular hypertrophy) and renal (renal failure). Furthermore, patient age was categorized into four age groups (▶ **Table 1**). Sample characteristics are given as absolute and relative frequencies or mean +/- standard deviation, whichever is appropriate.

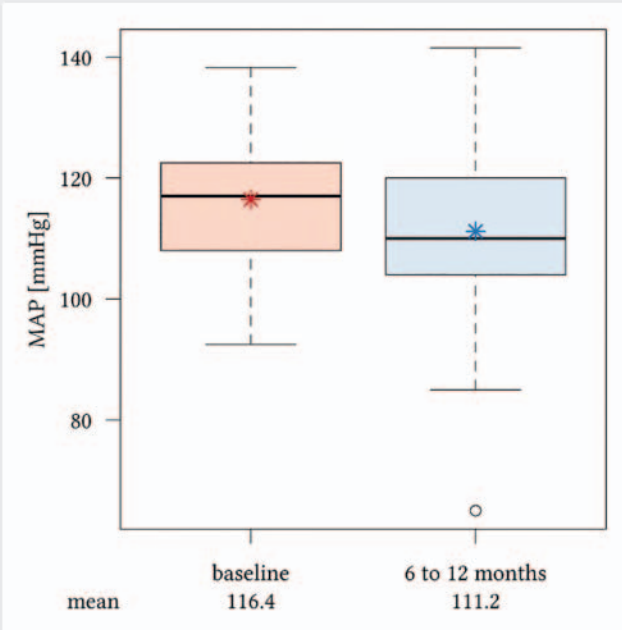
All three outcome parameters (BP, Cr and GFR) were analyzed separately, while the same modeling approach was performed. If necessary, the parameters were transformed by calculating the logarithmic values to meet the required model assumptions.

To analyze the course over post-intervention time for the outcome parameter, the change from baseline was modeled with a baseline-adjusted mixed effect model repeat measurement. The cluster structure was given by repeated measures within one patient due to the potential for several interventions and repeated measures within each intervention at different time points. The variables degree of renal dysfunction, gender, age, and degree of stenosis were included as predictors. Additionally, the respective interaction with the time interval of observation was included. Moreover, in all models Re-PTA and the five concomitant diseases, as described above, were added to control for potential confounding. A backward elimination for the predictors, their interaction term, and the confounder was performed using the likelihood ratio test for model comparison. For the final model we performed a multilevel model with patients as random effects and measurement variables as fixed effects. We reported regression coefficients, confidence intervals for regression coefficients, and the corresponding p-values.

All of the models present available case analyses. A two-tailed $p < 0.05$ was considered to be statistically significant. Nominal p-values are reported without correction for multiplicity. All of the analyses were performed using StataCorp Stata 15 (Texas, USA) and the statistical package R version 3.4.4 (The R Foundation for Statistical Computing, Vienna, Austria, 2018).

Results

The mid-term follow-up of creatinine levels was possible in 34 patients (33.7 %). The presence of comorbidities, age, gender, and degree of stenosis failed to show a significant correlation to renal outcome. No significant improvement in renal function could be observed in the follow-up (mean Cr drop −0.015 mg/dL; ▶ **Fig. 3**). However, higher baseline Cr levels were related to a steeper drop in Cr levels (p 0.002; difference to baseline −0.25 mg/dL, 95 %CI: −0.36, −0.07). Patients with advanced kidney failure and ipsilateral parenchymal atrophy showed, in comparison with milder degrees of renal insufficiency, a significant improvement in renal function in the follow-up (p 0.021, difference to baseline −0.33 mg/dL, 95 %CI: 0.05, −0.60). The follow-up GFR values show congruent results to Cr. The GFR showed a slight improvement in the follow-up (mean 0.019 ml/min). Lower baseline GFRs were related to higher GFR values in the follow-up (p 0.004; difference to baseline −0.20 ml/min, 95 %CI:-0.31, −0.04), and the patients with ipsilateral renal atrophy showed a significant therapeutic benefit (p 0.080; difference to baseline −0.31 ml/min, 95 % CI: −0.59, −0.01).



▶ **Fig. 4** A relevant drop in the mean arterial pressure (MAP) values 6–12 months after revascularization (mean 5.27 mmHg) could be observed.

▶ **Abb. 4** Ein relevanter Abfall des mittleren arteriellen Drucks (MAP) konnte 6–12 Monate nach der Revaskularisation (durchschnittlich 5,27 mmHg) nachgewiesen werden.

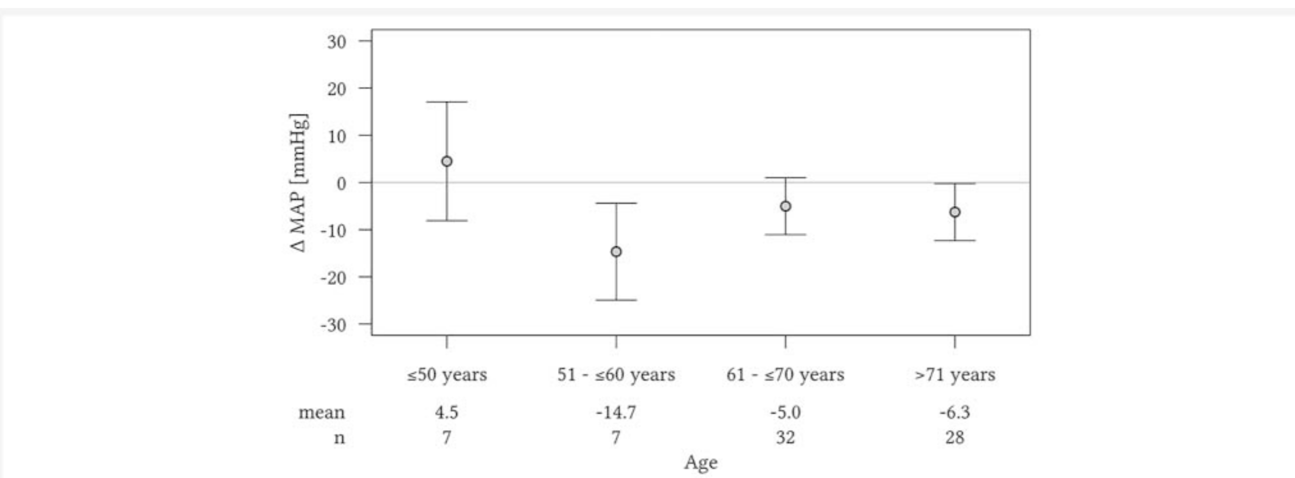
Mid-term BP values were available for analysis in 28 patients (27.7 %). A significant drop in MAP could be observed (mean −5.27 mmHg; ▶ **Fig. 4**). Higher baseline values showed a more pronounced drop in the follow-up BP values ($p < 0.001$; diff. to baseline −0.72 mmHg; 95 % CI: −1.4, −0.40). Patients with ages ranging from 51 to 60 years old showed a significant improvement in MAP (p 0.030; diff. to baseline −19.2 mmHg; 95 % CI: −34, −4.3; ▶ **Fig. 5**). The presence of comorbidities, gender, degree of stenosis, and degree of parenchymal atrophy failed to show a significant mid-term effect on the BP outcome.

Sufficient information about oral therapy was available in 95 patients (94 %). The average number of antihypertensives was 3.2 pre-PTA vs. 3.0 post-PTA (−0.2; p = ns). In 5 patients antihypertensive medication was discontinued after revascularization (4.9 %).

Discussion

The aim of this study was to analyze the effectiveness of stent angioplasty in patients with atherosclerotic renal artery stenosis in terms of renal function and blood pressure control. Possible interacting factors such as age, gender, comorbidities, degree of stenosis, and renal parenchyma atrophy were taken into consideration. In our patient collective we observed a statistically significant improvement in BP control after therapy, whereas no significant improvement in renal function could be seen. Nevertheless, we observed that higher baseline Cr and BP values were associated with significantly steeper drops in Cr and BP, respectively, in the follow-up. No interaction could be observed with gender, degree of stenosis, or presence of comorbidities.

RAS represents a complex entity with increasingly divergent results in the literature as to whether the revascularization is or is not associated with an improvement in renal function and BP control. CORAL, a recent large randomized clinical trial for RAS, similarly showed a statistically significant improvement in BP as well as



▶ **Fig. 5** Patients with ages ranging from 51–60 years showed a significantly better BP response to revascularization.

▶ **Abb. 5** Die Patienten der Altersgruppe zwischen 51–60 Jahren zeigten eine signifikant bessere Ansprechbarkeit des Blutdrucks auf eine Revaskularisation.

a reduction in medical therapy in patients undergoing revascularization [13]. From the 47 studies reviewed by Mousa et al., 37 (78.7 %) showed an improvement in BP control after revascularization [14]. Arthurs et al. described a decrease in the rate of renal injury and an improvement in blood pressure control, although the latter was limited to 6 months [15]. Another retrospective study showed that PTA was successful in reversing resistant hypertension in patients with atherosclerotic RAS and that the decline in GFR is associated with chronic kidney damage and is therefore irreversible [16].

To understand the reported divergence in BP results, it may be important to distinguish renovascular hypertension, which results from renal ischemia, from renal artery disease, which may or not be responsible for hypertension. While in renovascular hypertension revascularization is expected to improve blood pressure, in renal artery disease there may be no causal relationship between the two entities [1]. In a previous study, RAS was identified in only 14 % of patients with clinically suspected renovascular hypertension [17]. This may explain the relatively worse BP outcome in patients under 50 years old, who may present with other underlining pathologies. The studies on hypertension made by Goldblatt et al. in the 1930 s were essential to the understanding of the pathophysiological mechanism underlying renovascular hypertension and kidney injury. He stated that renal ischemia is responsible for an increase in the systemic arterial blood pressure, which is accompanied by a severe disturbance of renal function [18]. The activation of the renin-angiotensin-aldosterone system (RAAS) and the subsequent recruitment of additional pressor pathways as oxidative stress, sympathoadrenergic activation, and impaired vasodilatory responses are involved in the process of hypertensive parenchymal renal injury [19]. In ischemic renal damage, markers of inflammation may fail to decline after the restoring of tissue perfusion and oxygenation [11]. This may explain the absence of renal function improvement in our patient collective, as well as in larger clinical trials, such as ASTRAL and CORAL.

Previous studies have assessed the importance of appropriate patient selection [20, 21]. The Hercules trial failed to show a predictive value of per-procedural BNP in blood pressure change but stated that the PTRA may play an important role in appropriately selected patients [20, 22]. Establishment of reliable predictive factors of chronic kidney disease progression may be useful to predict long-term benefit of revascularization [21]. New noninvasive methods for the assessment of renal ischemia and irreversible tissue injury such as ratio of magnetic resonance parenchymal volume to isotopic single kidney glomerular filtration rate ratio [23] and blood oxygen level-dependent (BOLD) magnetic resonance imaging [11, 24] may be considered in the future for appropriate patient selection.

We retrospectively analyzed a large collective of patients for both RF and BP control taking into consideration different possible cofounding factors. Limitations of our study included the retrospective study design, the heterogeneous patient collective, the limited availability of follow-up data, and the absence of a control group of patients treated conservatively.

Renal artery stent angioplasty is a safe procedure [25]. In concordance with previous studies, there were no major adverse events and the rate of minor events was very low [26]. In contrast, both large prospective trials had a very high rate of major complications, ASTRAL with 9 % and CORAL with 13 % major stent-related complications. This might be due to the limited experience in some centers, which is only speculation but is supported by the low number of patients included in the study by those centers.

In conclusion, the highly divergent study results, and the absence of rigorously selected patients in the largest randomized trials indicate the need for the development of new study designs focused on appropriate patient selection. The cooperation between clinicians and interventional radiologists should be reinforced in order to develop multidisciplinary standardized protocols taking into consideration reliable predictive factors and to prevent obsolete interventions in unselected patient groups.

Conflict of Interest

The authors declare that they have no conflict of interest.

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