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Original Paper

Influence of SPRINT Study Type Automated Office Blood Pressure Measurements on Hypertension Diagnosis in Kidney Transplant Patients

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Key Words

Arterial Hypertension • Automated office blood pressure • Kidney transplantation

Abstract

Background/Aims: We compare conventional office blood pressure measurements with automated SPRINT-study type readings in kidney transplant recipients in order to determine the impact of the white coat effect in a prospective observational study. Methods: Adult patients with a functional renal transplant not dependent on dialysis were eligible. Readings were taken in the office in presence of the physician with an oscillometric method. Afterwards, readings were repeated with the patients resting alone in a quiet examination room with an automated blood pressure monitor. After 5 minutes of rest, 3 readings were taken at 1 minute intervals, with an average of these 3 readings calculated by the monitor. **Results:** 120 patients with an average age of 58.5±12.2 years were included. Mean time since transplantation was 7.95±6.48 years. Mean eGFR (CKD-EPI) was 48.5±18.3 ml/min. SPRINT-study type readings were significantly lower than office readings (139.01±18.45 vs. 149.00±21.02 mmHg systolic, p<0.001; 80.88±11.63 mmHg vs. 84.35±12.41 mmHg diastolic, p <0.001). Correlation analysis for many potentially influencing factors (diabetes mellitus, transplant vintage, proteinuria, age, immunosuppression, donor type) was not significant but obese women were significantly more prone to white coat hypertension. Conclusion: Automated office blood pressure measurements should be considered the method of choice in kidney transplant recipients.

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Introduction

Hypertension affects at least 90% of kidney transplant recipients [1]. It is a major risk factor for cardiovascular disease, graft dysfunction/failure and mortality [2, 3]. Thus, management of post-transplant hypertension is crucial to avoid long-term complications.

Most clinical trials on the treatment of arterial hypertension use office blood pressure measurements (oBP) [4,5] both as inclusion criteria and study end-points. In these trials, blood pressure is taken by manual or automated devices in outpatients coming to a study centre, as recommended by the ESC/ESH Guidelines for the management of arterial hypertension [6]. The target blood pressure as recommended by European [6] or US [7] guidelines largely depends on the results of the Hypertension Optimal Treatment (HOT) study [5]. This large trial with >18.000 participants measured blood pressure with an oscillometric device three times in a row in seated patients after 5min of rest. This and similar trials form the backbone of our knowledge about what is considered normal blood pressure and what blood pressure levels should be aimed at when using antihypertensive treatment [8].

Recently, the discussion about blood pressure goals was stimulated by the Systolic Blood Pressure Intervention Trial (SPRINT)[9]. The SPRINT study used a blood pressure measurement procedure that largely differs from earlier studies. Automated office blood pressure (AOBP) measurements without medical staff result in readings that are lower than regular office measurements. The extent of the difference between SPRINT and office measurements may be different for different patient groups. It has not yet been evaluated in adult kidney transplant patients. However, it is important to know the difference in order to apply SPRINT findings to transplant recipients.

There are several studies comparing ambulatory blood pressure monitoring (ABPM) and office blood pressure [10, 11] in individuals with normal renal function. Studies using 24h-blood pressure measurement devices indicated that the normal values are lower (average 10/5mmHg) than with regular office measurements [12]. It is well known that there is a so called "white coat" hypertension, i.e. higher blood pressure values are taken in the doctor's office than at home [13, 14]. The amount of this white-coat effect is largely different between individuals. Although white-coat hypertension itself has some prognostic impact on the patient [15], it is much less relevant than overt hypertension. It seems reasonable to keep the white coat effect in mind to avoid over-therapy in patients in whom this effect is particularly strong. In the general population, there are also contradictory results, demonstrating that AOBP and conventional office measurements may achieve comparable results at a familiar general practitioner's office [16].

Conventional office blood pressure measurement overestimates blood pressure in renal transplant patients reflecting the white coat effect [17, 18]. White coat effect is common in this population with around 65% of renal transplant recipients affected in a study using ABPM as reference (RETENAL study) [19].

In our study, we aim to compare oBP and AOBP in kidney transplant recipients to quantify the difference between regular office measurement and the SPRINT procedure (primary outcome). In addition, the study describes factors that might influence this difference (e.g. renal function, proteinuria, age, time since transplantation and use of immunosuppressive medication) (secondary outcomes).

Materials and Methods

We conducted a prospective study enrolling 120 outpatients between January and March 2017 at the kidney transplant centre of the Martin Luther University Medical Centre in Halle (Saale), Germany.

Patients with a functional renal transplant who were not dependent on dialysis treatment were eligible at ages between 18 and 99 years if they gave written informed consent. Further inclusion criteria were the possibility of Riva-Rocchi blood pressure measurement at least at one arm and the ability to give informed





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consent. Patients at pregnancy or lactation, or those with psychiatric disorders preventing from valid

consent. Patients at pregnancy or lactation, or those with psychiatric disorders preventing from valid informed consent were excluded from study participation.

Eligible patients were enrolled by the investigators consecutively in an unselected manner on the day of their routine outpatient clinic visit. All participants gave written and signed informed consent.

In all patients, conventional office blood pressure was assessed first. The measurement was taken in the presence of a doctor as a single reading after the patient sat for at least three minutes. Then, the patient was transferred into a quiet room, where he sat alone with the blood pressure monitor attached to his upper arm. After a delay of 5 minutes, the device took 3 readings at 1 minute intervals and calculated the average. For all measurements the automated blood pressure monitor used in the SPRINT study (HEM 907 XL, OMRON, OMRON Healthcare, Lake Forest, IL, USA) was applied. All measurements were done at the same day within a maximum period of 2 hours. The blood pressure cuffs were matched to patient arm circumferences according to the manufacturer's recommendation: 17-22cm=small size cuff; 22-32cm=medium size cuff and 32-42cm=large size cuff.

Demographic and medical data were collected from the medical charts and by interview. The following data were filed from each participant: age, gender, time since transplantation, type of transplant (deceased donor, living donor), weight, height, cause of end stage renal disease, concomitant diagnoses, complete list of medications including daily doses, creatinine, urinary protein, pre-transplant existing arterial hypertension.

All the kidney transplant patients took their blood pressure at home at least twice a day (in the morning and in the evening). We collected this data to compare home blood pressure to the other blood pressure measurements.

We defined the white coat hypertension as having a blood pressure >140/80 mmHg with conventional oBP and \leq 140/80 mmHg with AOBP measurements.

Statistical analysis

Data were analysed using the IBM SPSS Statistics 22 software package (IBM Corporation 2013, Somer, NY, USA) and the GraphPad Prism 5.03 statistical software package (GraphPad Software Inc., La Jolla, CA, United States). Paired T-tests were used to compare the two methods of BP measurement and Pearson correlations to study the influencing factors. Fisher's exact tests were used for contingency table analyses. Kruskal-Wallis tests with Dunn's multiple comparison tests were used for comparison of gender groups. Data are presented as mean ± SD. P<0.05 was considered as statistically significant.

The study was approved by the Ethics Committee of the medical faculty of the Martin Luther University Halle-Wittenberg on 19 April 2017 (Approval Nr. 2017-42) guided by the revised declaration of Helsinki (2013) and registered at *https://clinicaltrials.gov* (NCT00878033).

Results

We evaluated 120 kidney transplant patients whose characteristics are described in Table 1. End stage renal disease (ESRD) was due to chronic glomerulonephritis (n=36), polycystic kidney disease (n=19), hypertensive nephrosclerosis (n=18), IgA nephropathy (n=16), diabetic nephropathy (n=7), recurrent pyelonephritis (n=6), Alport's syndrome (n=5), Goodpasture syndrome (n=1), systemic lupus erythematosus (n=1), microscopic polyangiitis (n=1), nephrolithiasis (n=1) or unknown (n=9) renal disease.

With regard to the antihypertensive medication, 91 patients (76%) were treated with beta blockers, 68 patients (57%) with angiotensin receptor blockers, 59 patients (49%) with calcium channel blockers, 46 patients (38%) with diuretics, 21 patients (18%) with ACE inhibitors and 25 with others including moxonidin, urapidil, and spironolactone. Patients used 2.6 ± 1.2 antihypertensive medication classes.

The average systolic and diastolic AOBP were lower than the oBP measurements taken by the doctor with a mean difference of 9.9 ± 13.45 mmHg, p<0.001 and 3.47 ± 8.2 mmHg, p<0.001 (Table 2). 77% of Patients had inadequately high blood pressures (>140 mmHg systolic and/or >80 mmHg diastolic) at presentation according to oBP measurements. In



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contrast, with AOBP measurements, only 59% of patients had inadequately high values (p<0.0001).

There is also a significant difference between oBP measurements and measurements by the patients taken by themselves at home (Table 3).

In addition, there is also a significant difference between AOBP measurements and measurements by the patients taken by themselves at home (Table 4).

26 patients (21.7%) had white coat hypertension, defined as having a blood pressure >140/80 mmHg with conventional oBP and \leq 140/80 mmHg with AOBP measurements.

There was no relevant difference in blood pressure values between patients with or without calcineurin inhibitors in their immunosuppressive regimen (Table 5).

There was no significant correlation between blood pressure and tacrolimus level (systolic: r=-0.125, p=0.17; diastolic: r=0.099, p=0.28). Likewise, there were no significant correlations between blood pressure and other potentially influencing factors (diabetes mellitus, transplant vintage, proteinuria, age, CNI level, prednisolone dose, donor type; data not shown).

To further explore potential subgroups of patients who are prone to white coat hypertension, we divided the population according to their % difference (systolic or diastolic) between oBP and AOBP into two groups: oBP more than 10% higher than AOBP (diff+) or less than 10% higher or lower than AOBP (diff-). The proportion of diff+ females was significantly higher than that of diff+ males (58% vs. 35%, p=0.02, RR 0.56). In addition, diff+ females had significantly higher BMI than diff- females (28.88 vs. 24.77 kg/m², p=0.013), whereas diff+ and diff- males did not differ in BMI (25.89 vs. 25.82 kg/m², p=1.0).

Characteristics	Value
Age (years)	58.5 ± 12.2
Gender (M/F)	75/45
BMI (kg/m^2)	26.33 ± 4.68
Living donor	30 (25%)
Time after transplantation (years)	7.95 ± 6.48
Diabetes mellitus	27 (23%)
Creatinine (µmol/L)	141.6 ± 50.8
eGFR (CKD-EPI)	48.5 ± 18.3
Proteinuria (g/24h)	0.30 ± 0.57
Prednisolone use	92 (76.7%)
Prednisolone dose (mg/d)	3.33 ± 2.69
Triple immunosuppression	56 (46.7%)

Table 1. Demographic and clinical data of the patient population (n = 120)

Table 2. Comparisons between office blood pressure and automated office blood pressure measurements. oBP=office Blood Pressure, AOBP=automated office blood pressure, SBP=systolic blood pressure, DBP= diastolic blood pressure, p values from Student's t-test

	oBP (mmHg)	AOBP (mmHg)	Difference (mmHg)	p value
SBP	149.00 ± 21.02	139.01 ± 18.45	9.9 ± 13.45	p <0.001
DBP	84.35 ± 12.41	80.88 ± 11.63	3.47 ± 8.2	p <0.001

Table 3. Comparisons between office blood pressure and home blood pressure measurements . oBP= office blood pressure, BP= blood pressure, SBP=systolic blood pressure, DBP= diastolic blood pressure, p values from Student's t-test

	oBP (mmHg)	home BP (mmHg)	Difference (mmHg)	p value
SBP	149.00 ± 21.02	130.95 ± 11.77	18.05 ± 18.9	p <0.001
DBP	84.35 ± 12.41	78.80 ± 9.44	5.55 ± 11.37	p <0.001



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Table 4. Comparisons between automated office blood pressure and home blood pressure measurements. AOBP=automated office blood pressure, BP= blood pressure, SBP=systolic blood pressure, DBP= diastolic blood pressure, p values from Student's t-test

	AOBP (mmHg)	home BP (mmHg)	Difference (mmHg)	p value
SBP	139.01 ± 18.45	130.95 ± 11.77	8.06 ± 15.46	p <0.001
DBP	80.88 ± 11.63	78.80 ± 9.44	2.07 ± 9.9	p <0.025

Table 5. Comparison according to calcineurin inhibitor use. SBP=systolic blood pressure, DBP= diastolic blood pressure, CNI=calcineurin inhibitor, p values from Student's t-test

	CNI users	CNI free	Difference (mmHg)	p value
	(n=105)	(n=15)		p value
SBP	139.4 ± 19.1	136.3 ± 13	3.1 ± 5.1	p = 0.54
DBP	81.7 ± 11.7	75.3 ± 10.1	6.3 ± 3.2	p = 0.05

Discussion

While the framework for clinical decision making is mostly based on studies using office blood pressure readings, the SPRINT trial [9] recently used AOBP measurements. Patients were left alone in a quiet room with a programmed blood-pressure reading device that took readings of 1 minute intervals after 5 minutes of relaxing. SPRINT included more than 9.300 cardiovascular high-risk individuals without diabetes mellitus. It was a randomized prospective trial with intervention aiming at a low (<120 mmHg) vs. standard (<140 mmHg) systolic blood pressure. The trial was stopped early because of the large benefit of the intervention on the combined cardiovascular end-point. Since publication of this study, there is a vivid scientific discussion whether the low blood pressure goal should be aimed at in different patient populations.

Recent studies confirmed that the blood pressure readings taken with the SPRINT technique are relevantly lower than the readings with regular office blood pressure measurements [20]. In this study in a large random population sample, the SBP (systolic blood pressure) and the DBP (diastolic blood pressure) was higher with conventional BP with a mean difference of 6.39 \pm 9.76 mmHg (systolic) and 2.50 \pm 6.54 mmHg (diastolic) respectively.

Another study using AOBP [17] in a general population showed the same results: the mean SBP and the mean DBP with the office BP was 140 ± 17 mmHg and 80 ± 11 mmHg. With the AOBP, values were significantly lower (SBP 132 ±19 and DBP 75 ±12 mmHg, p<0.001).

In patients with chronic kidney disease, AOBP was also evaluated [21]. It was shown that the AOBP readings were lower by 10.1±12.2 mmHg (SBP) and 2.8±10.6 mmHg (DBP) compared to office BP readings.

Patients after renal transplantation very frequently have arterial hypertension [3]. This is in part induced by the kidney disease or effects of the transplant and the immunosuppressive therapy; thus it might be considered a form of secondary hypertension. The KDIGO guideline 2009 [22] recommends to maintain blood pressure <130/80 mmHg in these patients. This recommendation is based on analogy to data from the general population and has not been formally proven in transplant patients. In order to determine if the SPRINT results can be extrapolated to transplant recipients as well, it is important to show the effect size of the different blood pressure measurement techniques (AOBP vs. conventional oBP) in this



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particular patient group. An accurate measurement of blood pressure is needed to avoid over-prescription of antihypertensive medication, to avoid hypotension, drug interactions and last but not least non-adherence and non-observance.

Recent recommendations around the world now suggest AOBP as the method of choice for office BP measurements. The CHEP (Canadian Hypertension Education Program) guidelines [23] 2016 recommend AOBP as the preferred method of performing in-office BP measurements with the criteria of diagnosis as SBP >135 mmHg and DBP >85 mmHg. This is based on the fact that several studies have shown that AOBP is comparable to ABPM (ambulatory BP measurements) [24-26]. Likewise, the European society of Hypertension and the European society of Cardiology [6] recommend in 2013 the automated office BP if feasible. The latest recommendation from KDIGO 2012 [27] do not give any statement on AOBP in the kidney transplant patients.

To our knowledge, the present study is the first that evaluated the use of AOBP among kidney transplant recipients in a large cohort. We have demonstrated that AOBP measurements significantly differ from conventional office measurements in this vulnerable patient population. Systolic and diastolic office blood pressures are higher than the respective AOBP measurements due to the white coat effect. Based on our results, we have estimated the prevalence of the white coat effect up to 21%, pronouncing the need for more valid test procedures as like AOBP. According to our results, especially women with higher BMI are more prone to white coat hypertension.

Conclusion

We conclude that accurate measurement of blood pressure is essential for the management of arterial hypertension in renal transplantation patients. We confirmed the ability of AOBP to eliminate the office induced, so called white coat hypertension. Therefore, AOBP should be considered the method of choice for office blood pressure measurements in kidney transplant recipients, especially obese women.

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Disclosure Statement

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