Diagnostic Performance of Blood Pressure Measurement Modalities in Living Kidney Donor Candidates

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Abstract

Background and objectives Precise BP measurement to exclude hypertension is critical in evaluating potential living kidney donors. Ambulatory BP monitoring is considered the gold standard method for diagnosing hypertension, but it is cumbersome to perform. We sought to determine whether lower BP cutoffs using office and automated BP would reduce the rate of missed hypertension in potential living donors.

Design, setting, participants, & measurements We measured BP in 578 prospective donors using three modalities: (*1*) single office BP, (2) office automated BP (average of five consecutive automated readings separated by 1 minute), and (*3*) ambulatory BP. Daytime ambulatory BP was considered the gold standard for diagnosing hypertension. We assessed both the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) and the American College of Cardiology/American Heart Association (ACC/AHA) definitions of hypertension in the cohort. Empirical thresholds of office BP and automated BP for the detection of ambulatory BP–diagnosed hypertension were derived using Youden index, which maximizes the sum of sensitivity and specificity and gives equal weight to false positive and false negative values.

Results Hypertension was diagnosed in 90 (16%) prospective donors by JNC-7 criteria and 198 (34%) prospective donors by ACC/AHA criteria. Masked hypertension was found in 3% of the total cohort by JNC-7 using the combination of office or automated BP, and it was seen in 24% by ACC/AHA guidelines. Using Youden index, cutoffs were derived for both office and automated BP using JNC-7 (<123/82 and <120/78 mm Hg) and ACC/AHA (<119/79 and <116/76 mm Hg) definitions. Using these lower cutoffs, the sensitivity for detecting hypertension improved from 79% to 87% for JNC-7 and from 32% to 87% by ACC/AHA definition, with negative predictive values of 95% and 87%, respectively. Missed (masked) hypertension was reduced to 2% and 4% of the entire cohort by JNC-7and ACC/AHA, respectively.

Conclusions The prevalence of hypertension was higher in living donor candidates using ACC/AHA compared JNC-7 definitions. Lower BP cutoffs in the clinic improved sensitivity and led to a low overall prevalence of missed hypertension in prospective living kidney donors.

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Introduction

Living donor kidney transplantation is the treatment of choice for patients with ESKD. The success of living donation depends on not only the advantages to the recipient but also, the continued long-term wellbeing of the donor (1). The living donor population is carefully prescreened for the absence of a history of overt uncontrolled hypertension. Those with controlled hypertension without signs of end organ damage may be considered donor candidates, particularly if they are older donor candidates, provided that they have appropriate screening and follow-up (2). Therefore, detailed BP assessment is crucial during the evaluation of prospective living donors.

Clinic BP measurements typically are the basis for clinical screening. However, they exhibit considerable variability, and the measurements are complicated by the occurrence of masked or white coat hypertension. Ambulatory BP monitoring is considered the gold standard technique for BP assessment, because its use has been shown to correlate better with cardiovascular risk than conventional office-based BP (3–5). One analysis of living kidney donor candidates found a better correlation with end organ damage with hypertension diagnosis by ambulatory versus office BP (5). Ommen *et al.* (6) suggested the routine use of ambulatory BP in evaluating living kidney donors, because it permits the detection of white coat and masked hypertension. However, the use of ambulatory BP monitoring has not been implemented widely by transplant programs, because this method is costly and may be cumbersome. Furthermore, many health care plans do not cover this procedure (7). The use of automated office-based BP measurement devices, which take the average of

multiple consecutive office BP readings, has been reported to correlate well with daytime ambulatory BP readings and reduce the white coat response (8–13). Routine ambulatory BP monitoring, which adds time and cost to the evaluation process, may not always be needed for the evaluation of prospective living donors. A detailed characterization of BP measurements and diagnosis of hypertension using various modalities in potential living donors has not been previously well described.

The aims of this study are to describe the BP characteristics of potential living donors using three different modalities: (*1*) office BP (single reading measured using an aneroid sphygmomanometer in the office), (*2*) automated BP (average of five automated consecutive office BP readings), and (*3*) average daytime ambulatory BP. We further sought to determine whether optimal lower cutoffs for office and automated BP could lead to a reduction in missed or masked hypertension in prospective donors.

Materials and Methods

This study was approved by the Institutional Review Board at the Cleveland Clinic. A historical chart review was performed on 634 consecutive potential living donors age 18 years old and older from May 2009 to December 2016. We identified 578 potential donors in whom BP was measured using all three modalities during their initial evaluation.

Living Donor BP Measurements

Office BP was obtained by trained clinic staff following the American Heart Association (AHA) guidelines using an automated oscillometric aneroid sphygmomanometer (14). Automated BP was measured using the BpTRU device (BpTRU; VSM MedTech Ltd., Coquitlam, BC, Canada), which is designed to take an initial reading with the clinic staff present in the room with the donor and then, take five measurements at intervals of 1 minute with the subject alone in the room; the average of the last five readings is used as the actual BP reading (15). Ambulatory daytime BP was measured every 20 minutes during the day using an automated BP monitor fitted on the arm at the time of the clinic visit.

The diagnosis of hypertension was categorized first according to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) (16), which defined hypertension by office BP as ≥140/90 mm Hg, hypertension by automated office BP as ≥135/85 mm Hg, and hypertension by home daytime ambulatory BP as ≥135/85 mm Hg. The cutoff of ≥135/85 mm Hg for automated BP was on the basis of recent Canadian guidelines (17). In addition, definitions from the 2017 American College of Cardiology (ACC)/AHA High BP Clinical Practice Guideline were used, defining hypertension by office BP, automated BP, and ambulatory BP as ≥130/80 mm Hg (18).

White coat hypertension was defined as potential donors with hypertension by office BP or automated BP methods but not by ambulatory BP. Masked hypertension was defined as potential donors with normal BP by office BP or automated BP methods but hypertension by ambulatory testing. Sustained hypertension was defined as hypertension by either office BP or automated BP methods, along with hypertension by ambulatory BP.

Statistical Analyses: BP Classification According to Guidelines (Existing Method Analyses)

Existing methods of determining hypertension from office and automated BP measurements involved choosing cutoffs and determining whether either systolic or diastolic BP was above a certain cutoff. BP was analyzed using both JNC-7 and ACC/AHA guidelines.

The definition of hypertension on the basis of JNC-7 guidelines was an office systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg or an automated systolic BP ≥135 mm Hg or diastolic BP ≥85 mm Hg. The gold standard for hypertension was defined as an average daytime ambulatory systolic BP ≥135 mm Hg or diastolic BP ≥85 mm Hg.

The definition of hypertension on the basis of ACC/AHA guidelines was an office or automated systolic BP ≥130 mm Hg or diastolic BP ≥80 mm Hg. The gold standard for hypertension was defined as an average daytime ambulatory systolic BP ≥130 mm Hg or diastolic BP ≥80 mm Hg.

The mean and SD were reported for continuous variables. Frequency and proportion were reported for categorical variables. The diagnostic performances (sensitivity, specificity, positive predictive value, and negative predictive value) of the cutoff values were derived from a contingency table with bootstrap-derived 95% confidence intervals.

Optimal cutoff points for systolic and diastolic BP were calculated using Youden statistic. Youden *J* statistic (or Youden index) captures the performance of a binary diagnostic test. It can take a value that ranges from zero to one, with one indicating no false positive or false negative values. Thus, it takes into account both true positive and negative values. The goal was to maximize the Youden statistic (Youden index = sensitivity + specificity −1). Youden index gives equal weight to false positive and false negative values. Optimal cutoff points were defined as points that maximize the Youden index. These points were calculated for each diagnostic tool (office BP monitor, automated BP monitor, and combined office and automated monitoring). The performance of each of these tools was compared with the

Table 1. Characteristics of prospective living kidney donors

Characteristics	*n*=578
Age, yr	43±11
Men, *n* (%)	254 (44)
Black race, *n* (%)	62 (11)
BMI, kg/m^2	27±4
Current smoker, *n* (%)	137 (23)
Serum creatinine, mg/dl	0.9±0.2
Iothalamate GFR, ml/min per 1.73 m^2	102±20
Office systolic BP, mm Hg	119±15
Office diastolic BP, mm Hg	77±10
Automated systolic BP, mm Hg	114±12
Automated diastolic BP, mm Hg	74±9
Daytime ambulatory systolic BP, mm Hg	123±10
Daytime ambulatory diastolic BP, mm Hg	77±7

BMI, body mass index.

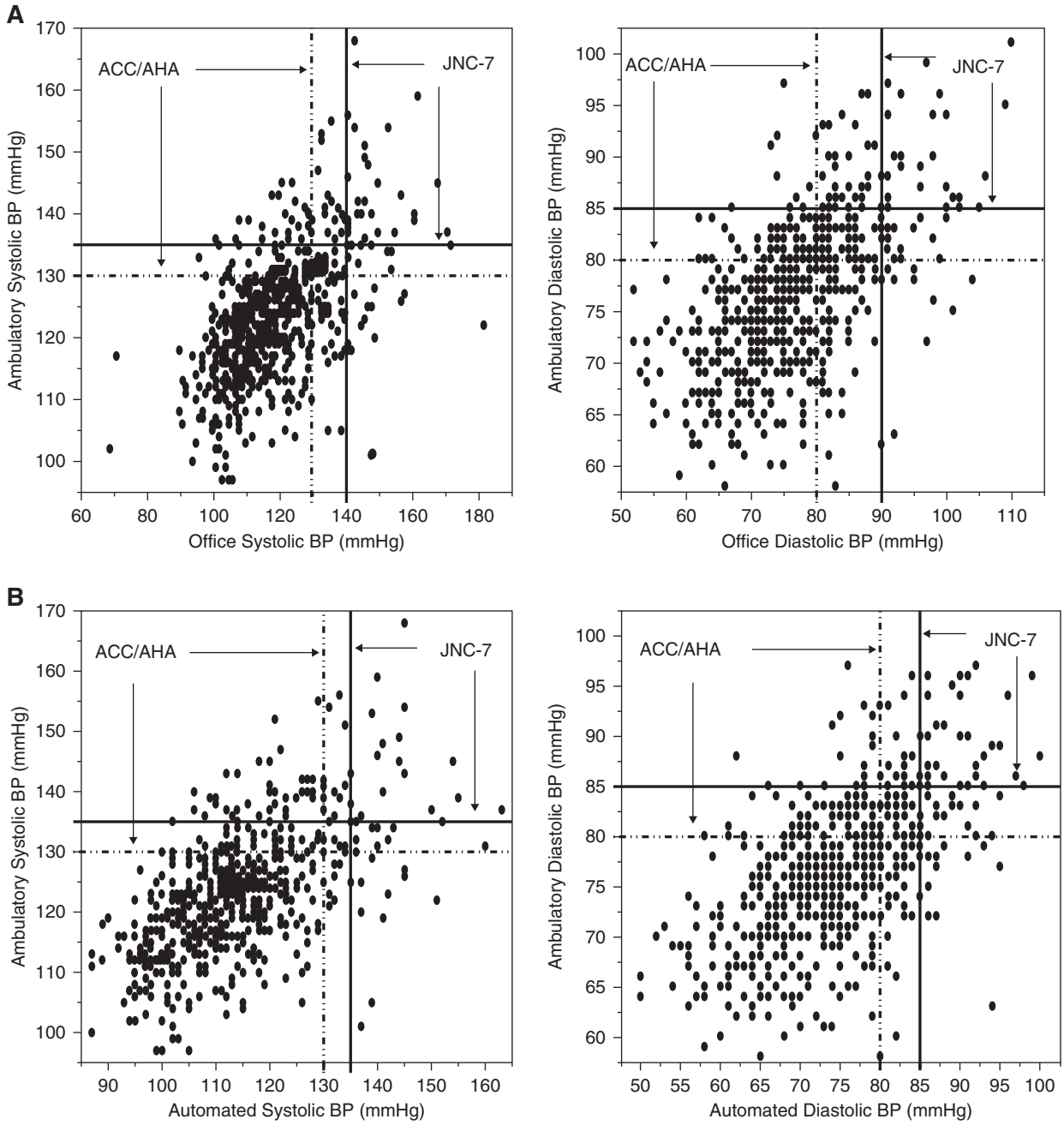

Figure 1. | **Scatter plots for (A) office and (B) ambulatory systolic and diastolic BP (*x* axes) and corresponding ambulatory BP (*y* axes).** Solid lines show the cutoffs for Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) hypertension. Dashed lines show the cutoffs for American College of Cardiology/American Heart Association (ACC/AHA) hypertension.

average daytime BP (gold standard). For the gold standard, hypertension was defined once using the JNC-7 and once using ACC/AHA guidelines. Thus, two models were assessed for each tool. Bootstrapping (using 200 bootstrapped samples) was used to reduce bias when calculating the optimal cutoff points for each of the four models. Performance of the six resulting models was assessed using various metrics, such as sensitivity, specificity, positive predictive value, and negative predictive value. Bootstrapped confidence intervals were calculated for these parameters. Analysis was performed using cutpointr and pROC packages in R studio v 1.1.53.

Results

Population Characteristics

Characteristics of prospective living kidney donors are reported in Table 1. Hypertension was defined by the gold standard of daytime ambulatory BP. Following the JNC-7 definition of hypertension (ambulatory daytime

Table 2. Performance of office BP and ambulatory BP for the diagnosis of hypertension as determined using 24-hour BP monitoring using standard BP thresholds

BP Classification and Modality	Sensitivity	Specificity	Negative Predictive Value	Positive Predictive Value
JNC-7				
Office BP	0.45 (0.38 to 0.58)	0.92 (0.92 to 0.96)	0.88 (0.89 to 0.93)	0.60 (0.48 to 0.72)
Automated BP	0.48 (0.38 to 0.58)	0.91 (0.88 to 0.93)	0.90 (0.88 to 0.93)	0.48 (0.38 to 0.59)
Office or automated BP	0.79 (0.69 to 0.86)	0.67 (0.63 to 0.71)	0.95 (0.92 to 0.96)	0.31 (0.25 to 0.37)
ACC/AHA				
Office BP	0.29 (0.23 to 0.35)	0.96 (0.94 to 0.98)	0.72 (0.68 to 0.76)	0.81 (0.71 to 0.91)
Automated BP	0.16 (0.1 to 0.22)	0.98 (0.96 to 1)	0.69 (0.65 to 0.73)	0.84 (0.72 to 0.96)
Office or automated BP	0.32 (0.26 to 0.38)	0.96 (0.94 to 0.98)	0.73 (0.69 to 0.77)	0.81 (0.73 to 0.89)

Office or automated BP is defined by either office or automated BP measurements exceeding the cutoff for normotension by the BP classification. 95% confidence intervals are shown in parentheses. JNC-7, Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; ACC/AHA, American College of Cardiology/American Heart Association.

BP ≥135/85 mm Hg), 90 of 578 (16%) donor candidates had hypertension, and using the ACC/AHA definition of hypertension (ambulatory daytime BP ≥130/80 mm Hg), 198 of 578 (34%) donor candidates had hypertension. Of the 578 donor candidates screened, 340 (59%) ultimately donated a kidney. Of the 90 donors who were diagnosed with hypertension by the JNC-7 definition during their evaluation, 50 were excluded from donation, whereas the remaining 40 (44%) proceeded with donation after achieving additional management and control of their hypertension. By the ACC/AHA definition, 104 of 198 (52%) donor candidates with hypertension proceeded with donation.

BP Classification According to BP Modalities

The relationships between office BP and BpTRU BP with ambulatory blood pressure monitoring for each donor are illustrated in Figure 1 showing office cutoffs for hypertension by JNC-7 and ACC/AHA criteria. Using JNC-7 definitions, white coat hypertension was more common with automated BP (8% of the entire cohort) versus office BP, which used a higher cutoff (5%). The prevalence of masked hypertension was 8% by both office modalities. By the ACC/AHA definition, white coat hypertension was found in just 3% by office and automated BP, whereas the prevalence of masked hypertension increased to 31% by office BP and 28% by automated BP.

The predictive performances of office and automated BP were evaluated in the 578 donor candidates using the predefined cutoffs, with results from each model presented in Table 2. The existing guidelines revealed high levels of specificity, indicating that most of the donor candidates predicted to have hypertension were hypertensive by ambulatory BP. However, there were low levels of sensitivity, indicating that many donor candidates with hypertension were not detected by office and automated BP. Sensitivity improved after combining office and automated BP cutoffs to predict hypertension. Receiver operating characteristic curves for office, automated, and combined modalities using JNC-7 and ACC/AHA definitions are shown in Supplemental Figures 1 and 2.

Determination of Optimal Cutoffs

Optimal cutoffs were determined as defined by using the Youden index, and the prediction results are depicted in Table 3. The resulting models had improved sensitivity for the diagnosis of hypertension, although the specificity was reduced using these cutoffs (Table 4). When including both office and ambulatory BP readings, the sensitivity using JNC-7 improved from 79% to 87%, and the sensitivity using the ACC/AHA guidelines improved from 32% to 87%. The negative predictive value below the optimal cutoffs remained at 95% for JNC-7 guidelines and improved from 73% to 87% by ACC/AHA guidelines.

Figure 2 shows the proportion of patients with sustained hypertension, masked hypertension, white coat hypertension, and sustained normotension for office and automated readings relative to the ambulatory gold standard BP. Figure 2A shows proportions using JNC-7 cutoffs, and Figure 2B shows proportions using ACC/AHA cutoffs.

Table 3. Empirical new BP thresholds derived to optimize the sensitivity and specificity of diagnosing hypertension as determined using 24-hour BP monitoring

BP Classification	Office Systolic BP	Office Diastolic BP	Automated Systolic BP	Automated Diastolic BP
JNC-7	123	82	120	78
ACC/AHA	119	79	116	76

JNC-7, Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; ACC/AHA, American College of Cardiology/American Heart Association.

Table 4. Performance of empirical new BP thresholds for the diagnosis of hypertension as determined using 24-hour BP monitoring

BP Classification and Modality	Sensitivity	Specificity	Negative Predictive Value	Positive Predictive Value
JNC-7				
Office BP	0.81 (0.74 to 0.89)	0.67 (0.63 to 0.71)	0.94 (0.92 to 0.96)	0.36 (0.33 to 0.4)
Automated BP	0.78 (0.7 to 0.86)	0.68 (0.64 to 0.72)	0.93 (0.91 to 0.95)	0.36 (0.32 to 0.4)
Office or automated BP	0.87 (0.81 to 0.93)	0.59 (0.55 to 0.64)	0.95 (0.93 to 0.97)	0.33 (0.3 to 0.36)
ACC/AHA				
Office BP	0.82 (0.77 to 0.87)	0.62 (0.57 to 0.67)	0.84 (0.8 to 0.88)	0.59 (0.55 to 0.63)
Automated BP	0.77 (0.71 to 0.82)	0.65 (0.6 to 0.7)	0.8 (0.77 to 0.85)	0.6 (0.56 to 0.64)
Office or automated BP	0.87 (0.83 to 0.91)	0.55 (0.5 to 0.61)	0.87 (0.82 to 0.91)	0.56 (0.53 to 0.6)

Office or automated BP is defined by either office or automated BP measurements exceeding the cutoff for normotension by the BP classification. Thresholds for hypertension by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) are ≥123/82 mm Hg for office BP and ≥120/78 mm Hg for automated BP. Thresholds for hypertension by the American College of Cardiology/American Heart Association (ACC/AHA) are ≥119/79 mm Hg for office BP and ≥116/76 mm Hg by automated BP. 95% confidence intervals are shown in parentheses.

At optimal cutoffs, shown in the bar graphs in Figure 2, right panels, the prevalence of masked hypertension dropped, particularly when both cutoffs for office and automated BP were met. Using optimal cutoffs, masked hypertension by combined office and ambulatory readings (both below the optimal cutoff) was reduced to 2% of the entire cohort by the JNC-7 ambulatory cutoff and 4% by the ACC/AHA ambulatory cutoff. Receiver operating characteristic curves for office and automated modalities compared with the gold standard ambulatory BP by JNC-7 and ACC/AHA definitions are shown in Figure 3.

Discussion

In this analysis of 578 living kidney donor candidates, we used daytime ambulatory BP as the gold standard and found a 16% prevalence of hypertension using JNC-7 criteria. This percentage increased to 34% using the recently published ACC/AHA guidelines (18). Utilization of office and automated office BP measurements demonstrated a high level of specificity but low sensitivity and a high percentage of patients with masked hypertension. Using optimal lower cutoffs that provided the best performance for office and automated BP led to an improvement in sensitivity and a reduction in missed (masked) hypertension in prospective living donors. The lowest percentage of masked hypertension was seen using optimal cutoffs and combining office modalities when both office and automated BP were below the redefined cutoffs. This led to prevalence of masked hypertension in just 2% and 4% of the entire donor cohort by JNC-7 and ACC/AHA guidelines, respectively. Specificity was reduced by using lower office and automated cutoffs, but an appropriate goal with living donor candidates is to avoid missing hypertension by office and automated readings. Using lower screening cutoffs may help to define those who would most benefit from ambulatory monitoring.

Textor *et al.* (19) originally described the utility of daytime average ambulatory blood pressure monitoring to identify white coat hypertension in a cohort of living donors, with approximately two thirds of those with high BP in the clinic having normal BP at home. We found a lower prevalence of white coat hypertension, but percentages were higher when combining office and automated modalities and substantially higher when using lower optimal cutoffs. Thus, ambulatory BP measurements seem to remain valuable to screen for white coat hypertension in prospective living kidney donors. There is some concern that white coat hypertension alone may predict adverse cardiovascular outcomes (20), although a recent analysis identified higher cardiovascular risk associated with white coat hypertension only in older patients with three or more additional cardiac risk factors (21).

Masked hypertension is associated with cardiovascular risk and mortality at levels comparable with those seen in patients with sustained hypertension, and it is more common in men, older patients, and patients with borderline office BP (22–24). In one analysis, the prevalence of masked hypertension was low at 3.9% when office BP was <120/80 mm Hg but notably higher at 34.1% in patients with higher "normal" BP by office BP (24). We similarly noted that, when lower optimal cutoffs (approximating 120/80 mm Hg) were used for office and automated readings, the proportion of donor candidates with missed (masked) hypertension dropped significantly. Approximately one third to one half of the donor candidates had BP below these lower cutoffs by both office and automated modalities. Given the high prevalence of masked hypertension above these cutoffs, particularly when using ACC/AHA guidelines, we would advocate for ambulatory BP monitoring in donor candidates above these optimal cutoffs.

One challenge in interpreting these data relates to the evolving guidelines and definitions of hypertension. Donor selection in our transplant center previously relied on the JNC-7 guidelines, and these may be still appropriate for living donor selection. The current Kidney Disease Improving Global Outcomes (KDIGO) guidelines for living donor selection state that normal BP, as defined by guidelines for the general population in the country or region where donation is planned, is acceptable for donation (25). The KDIGO guidelines go on to say that donor candidates with hypertension that can be controlled to systolic BP <140 mm Hg and diastolic BP <90 mm Hg using one or two antihypertensive agents, with no evidence of target organ damage, may be acceptable for donation.

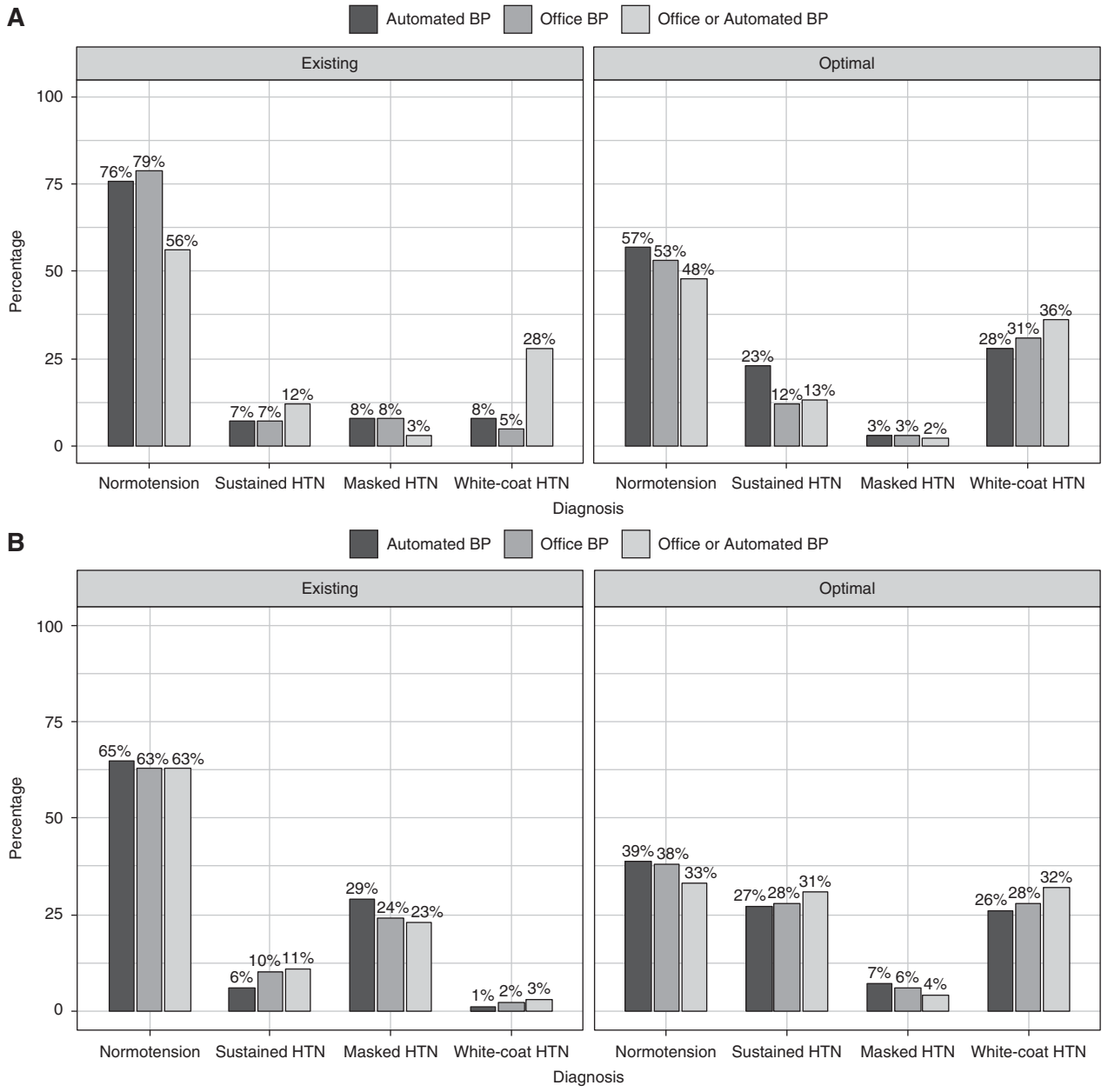

Figure 2. | Bar graphs showing the proportions of donor candidates with sustained normotension, sustained hypertension (HTN), masked HTN, and white coat HTN using (A) Joint National Committee 7 and (B) American College of Cardiology/American Heart Association criteria for office BP, automated BP, and combined office and automated BP. The combined values indicate whether either office or automated BP was above the cutoff for HTN. The bar graphs in the right panel show the categories of BP using the optimal cutoffs described in Table 3 (A): (office BP <123/82 mm Hg; automated BP <120/78 mm Hg), and (B): (office BP <119/79 mm Hg; automated BP <116/76 mm Hg).

A potential concern with adopting the recent ACC/AHA definition is that substantially more living donor candidates would be defined as hypertensive. The prevalence of hypertension almost doubled when converting from JNC-7 to ACC/AHA definitions in our cohort (16%–34%). Some have suggested maintaining less stringent definitions of hypertension and targets for therapy in healthy adults (26). We allowed some donors with hypertension by JNC-7 criteria to donate provided that there was no evidence of end organ damage by electrocardiogram and/or echocardiogram and provided that their BP normalized with lifestyle modification or single drug therapy.

Regardless, long-term follow-up and BP monitoring after living donation is paramount for all living donors, with perhaps even closer monitoring of donors with hypertension. One prior analysis found that kidney donors with hypertension, defined by BP>140/90 mm Hg or treatment for hypertension, had more glomerulosclerosis on implantation biopsies (27). Another study found a greater risk of long-term mortality after living donation in donors with a systolic BP ≥140 mm Hg compared with those with systolic BP <120 mm Hg (28). Additional analysis is required to determine whether such findings are also associated with

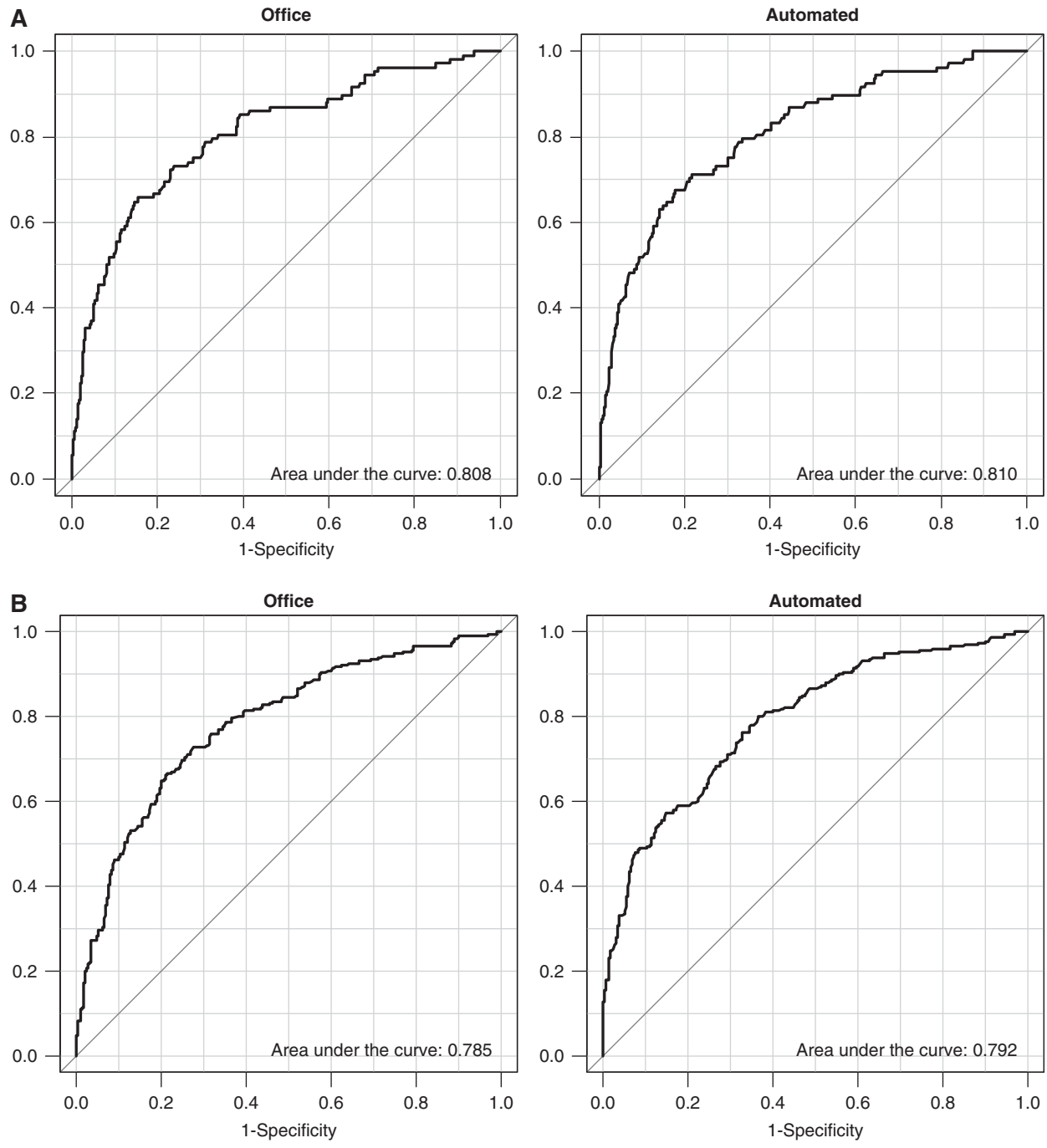

Figure 3. | **Receiver operating characteristic curves showing the performance of office and automated BP.** (A) The gold standard is on the basis of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines for daytime ambulatory systolic BP ≥135 mm Hg or diastolic BP ≥85 mm Hg. (B) The gold standard is on the basis of the American College of Cardiology/American Heart Association guidelines for daytime ambulatory systolic BP ≥130 mm Hg or diastolic BP ≥80 mm Hg.

hypertension defined by more stringent guidelines. Regardless, vigilance is required with long-term follow-up and monitoring of BP in all living donors after donation.

This study has several limitations. First, it is a retrospective, single-center study of potential living kidney donors, and hence, generalization to the general population undergoing evaluation may not be valid. Second, there was only a single clinic visit during which office and automated BP values were measured, and office BP was only a single isolated reading. Third, we did not analyze 24-hour ambulatory BP readings, because we sought to compare daytime ambulatory readings with office and automated BP.

In conclusion, we found that office BP and automated BP are not sufficient to rule out hypertension in living kidney donor candidates using routine cutoffs and definitions,

illustrating the value of ambulatory BP in screening of living donors. Using lower optimal cutoffs improved the sensitivity of office readings and reduced the prevalence of masked hypertension in donor candidates to a low percentage. Donor candidates above these lower office and automated cutoffs may benefit the most from ambulatory monitoring to avoid missing hypertension in the office setting.

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Disclosures

None.

Supplemental Material

This article contains the following supplemental material online at http://cjasn.asnjournals.org/lookup/suppl/doi: 10.2215/CJN.02780218/-/DCSupplemental.

Figure 1. Performance of office, automated, and combined office and automated BP for the gold standard of home ambulatory daytime BP using JNC-7 guidelines.

Figure 2. Performance of office, automated, and combined office and automated BP for the gold standard of home ambulatory daytime BP using ACC/AHA guidelines.

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