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## Differential Treatment of Hypertension by Primary Care Providers and Hypertension Specialists in a Barber-Based Intervention Trial to Control Hypertension in Black Men

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### Abstract

Black men have less physician contact than other groups and thus lower rates of hypertension treatment and control. In the BARBER-1 trial, hypertension control in 8 active-intervention barbershops where barbers offered blood pressure (BP) checks with haircuts and motivated black male patrons with high BP to seek provider follow-up showed a small improvement over that in 7 comparison shops where patrons received hypertension pamphlets but not barber-BP checks. Under-treatment of hypertension, which is common in primary care, may have impacted the outcomes. Thus, in patrons with baseline systolic BP  $\geq 140$  mmHg and 10-month follow-up including BP and medication data, we performed post-hoc comparison of systolic BP reduction between comparison-arm patrons ( $n=68$ ) treated by primary care providers (PCPs) with a) intervention-arm patrons ( $n=37$ ) treated by PCPs, or b) intervention-arm patrons ( $n=33$ ) who lacked access to PCPs and were treated by hypertension specialist physicians serving as safety-net providers. The latter group had higher baseline systolic BP than the others ( $162\pm 3$  vs.  $155\pm 2$  and  $154\pm 2$  mmHg, respectively,  $p<0.01$ ). After adjustment for baseline systolic BP and other covariates, systolic BP reduction was  $21\pm 4$  mmHg greater than in the comparison group ( $p<.0001$ ) when barbers referred patrons to hypertension specialists but no different when they referred to PCPs ( $4\pm 4$  mmHg,  $p=0.31$ ). Specialist-treated patrons received more BP medication and different classes of medication than PCP-treated patrons. In conclusion, the barber-based intervention—if connected directly to specialty-level medical care—could have a large public health impact on hypertensive disease in black men.

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## Keywords

Hypertension; African-Americans; Gender; Antihypertensive Medication

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Hypertension is particularly devastating to non-Hispanic black men, who have a higher prevalence of hypertension than most other groups but less physician contact, leading to low rates of hypertension awareness, treatment, and control.<sup>1-6</sup> As a result, black men have the highest hypertension death rate of any U.S. race, ethnic, or gender group.<sup>4,7</sup> We conducted a cluster-randomized trial of a hypertension control program implemented through black-owned barbershops, enlisting barbers to monitor blood pressure (BP) and promote provider follow-up for uncontrolled hypertension. In this trial (Barber-Assisted Reduction in Blood Pressure among Ethnic Residents [BARBER-1]),<sup>8</sup> we observed a small intervention effect on systolic BP, indicating that further research is needed to develop a more potent intervention model.<sup>8,9</sup> We previously reported a high level of adherence to the study protocol by the barbers and their patrons,<sup>8</sup> but had not examined the quality of medical care delivered by the patrons' healthcare providers.

Under-treatment of hypertension by office-based primary care providers (PCPs) is increasingly recognized as a key barrier to hypertension control,<sup>10-12</sup> both in provider networks and national databases,<sup>13</sup> and thus constitutes one hypothesis to explain the smaller than desired effect size in the BARBER-1 trial. To test this hypothesis, we conducted a post-hoc subgroup analysis of BARBER-1 participants with unequivocally elevated baseline systolic BP and a completed exit interview. We compared systolic BP reductions and antihypertensive treatment regimens prescribed for hypertensive barbershop patrons in the comparison group—who received hypertension pamphlets and usual medical care by PCPs—with hypertensive patrons in the intervention group who followed their barbers' advice to seek medical follow up for high BP and had documented office visits with either: a) PCPs, or b) American Society of Hypertension-certified hypertension specialists. Using hypertension specialty care as a benchmark, we examined whether under-treatment of hypertension in primary care limited the ability of the barber-based intervention to lower systolic BP.

## Methods

In the BARBER-1 trial, patron consent was obtained and data were collected and stored in accordance with the guidelines of the Health Insurance Portability and Accountability Act. The study and analyses were approved by the Institutional Review Boards at the University of Texas Southwestern Medical Center, Temple University Institute for Survey Research, and Cedars-Sinai Medical Center.

The design and major outcomes of the BARBER-1 trial have been published.<sup>8,14</sup> Briefly, black male patrons of 17 black-owned barbershops in Dallas, Texas underwent baseline BP screening to identify those with hypertension and calculate an initial hypertension control rate for each shop (% with BP <135/85 or <130/80 if diabetic). All participants received written results of baseline BPs and detailed instructions for appropriate medical follow up. Then, shops were randomized to a comparison group that received hypertension pamphlets written for black patients by the American Heart Association or an intervention group in which barbers continually offered BP checks with haircuts and promoted physician follow-up with peer health messaging. We previously reported that, after 10 months, hypertension control improved, but systolic BP fell by only 2.5 mmHg more in the intervention group than in the comparison group (P=0.08), despite high levels of intervention fidelity by the barbers and acceptance by patrons.<sup>8</sup>

In this subsequent post-hoc analysis, we evaluated the potential impact of the quality of medical care received on systolic BP reduction in the BARBER-1 trial. We analyzed data from participants who completed the study and had a baseline systolic BP  $\geq 140$  mmHg; participants with baseline systolic BP  $<140$  mmHg were excluded from this analysis, because of unresolved controversy as to whether lower BP treatment thresholds lead to improved cardiovascular outcomes among black individuals or those with diabetes mellitus.<sup>15–17</sup> Data were analyzed in three subgroups of completers: (1) comparison-arm patrons all of whom were treated by PCPs, (2) intervention-arm patrons who followed their barbers' advice and had documented office visits with PCPs, and (3) intervention-arm patrons who followed their barbers' advice and had documented office visits with physicians who were certified as hypertension specialists by the American Society of Hypertension and were part of the study. The last subgroup of barbershop patrons had limited or no access to PCPs (either in private practice or in county or federally-funded safety net clinics) and were therefore referred to the academic medical center hypertension clinic, which agreed to provide discounted care (at a federally qualified health center rate) for uninsured study participants who were charged a co-pay of \$50 dollars for an initial office visit and \$25 for each follow-up visit.

The primary outcome was systolic BP reduction after 10 months. BP was measured in the barbershops by professional field interviewers using a validated oscillometric monitor (Welch Allyn, Arden, North Carolina).<sup>18</sup> They took 6 consecutive BP readings on each hypertensive subject on each of 2 days both at baseline and at the exit interview. The final four readings on the second day of each set were averaged to obtain stable mean values.<sup>1, 3</sup> Secondary outcomes, also assessed at the 10-month exit interview, included diastolic BP reduction, number and classes of BP medications in each participant's final antihypertensive regimen, and medication adherence, using the four-item Morisky questionnaire (with higher scores indicating high medication-taking adherence behaviors).<sup>19</sup> In the intervention group, interaction with a medical provider was documented by wallet-size provider referral cards the barbers gave to patrons with high BP readings; patrons received a free haircut for each card signed by their provider and returned to their barber. There was no objective means of documenting provider interaction in the comparison group.

Descriptive statistics are presented as simple means and standard errors. Unadjusted mean change in systolic BP and Kernel distributions were plotted for each of the three groups. Using ANOVA and standard linear and logistic multivariate regression models, statistical comparisons were made between a) intervention-arm patrons treated by hypertension specialists vs. comparison-arm patrons; b) intervention-arm patrons treated by community providers vs. comparison-arm patrons; and c) intervention-arm patrons treated by hypertension specialists vs. intervention-arm patrons treated by community providers. To model the primary outcome of systolic BP reduction, we assumed that missing final BP values were missing at random. Independent predictors of change in systolic BP were identified in linear regression models that adjusted for baseline systolic BP and other covariates (including age, education, marital status, smoking status and number of doctor visits; the latter was available only in the intervention group). The same approach was used to model secondary outcomes. Statistical significance was determined using the likelihood ratio test with a 2-sided alpha level of  $<.05$ . SAS, version 9.1.3 (© SAS Institute Inc., Cary, North Carolina and R, version 2.15.1 (© The R Foundation of Statistical Computing, [www.r-project.org](http://www.r-project.org)) were used for statistical analyses.

## Results

A total of 258 patrons in the intervention group and 227 patrons in the comparison group completed both the baseline and exit interviews. Of these, baseline systolic BP was  $\geq 140$

mmHg in 70 patrons in the intervention group (33 patrons treated by hypertension specialists and 37 patrons treated by PCPs) and 68 patrons in the comparison group all treated by PCPs.

Table 1 shows the baseline characteristics of these three groups. Intervention-arm participants who were treated by hypertension specialists were younger than comparison-arm participants and, though more were employed, fewer had health insurance or pre-existing PCPs and thus required a safety-net provider; they also had higher baseline systolic and diastolic BP. Intervention-arm participants who were treated by community PCPs were well matched with the comparison group except for a shorter duration of barbershop patronage.

The mean reduction in systolic BP was 2.6 times greater in intervention-group patrons treated by hypertension specialists than in the comparison group or in the intervention-group patrons treated by PCPs, whereas, the systolic BP reduction in intervention-group patrons treated by community PCPs was indistinguishable from that in the comparison group (Table 2 and Figure 1). After adjustment for baseline systolic BP and other covariates, systolic BP reduction was greater compared with the comparison group when barbers referred patrons to hypertension specialists but no different when they referred to PCPs (Figure 1). Other multivariate-adjusted independent predictors of greater systolic BP reduction were: (1) higher baseline systolic BP (  $\Delta$  systolic BP =  $-8 \pm 1$  mmHg per 10 mmHg elevation in baseline BP  $>140$  mmHg,  $p=0.003$  [  $-\text{coefficient} \pm \text{SE}$ ]); and (2) treatment with 3 or more BP medications (  $\Delta$  systolic BP =  $-9 \pm 3$  mmHg,  $p=0.003$ ). In contrast, neither medication adherence nor office visit frequency predicted systolic BP reduction. An intervention effect on diastolic BP reduction was also only seen in patrons treated by hypertension specialists (Table 2 and Figure 1).

Intervention-arm patrons who were referred to hypertension specialists received more BP medication than PCP-treated patrons in the comparison group; after adjustment for the higher baseline BP in the specialist-treated group, hypertension specialists prescribed one additional class of BP medication per antihypertensive regimen ( $p<0.002$ ). In contrast, PCPs prescribed the same amount of medication for patrons in intervention and comparison groups. A higher percentage of patrons referred to hypertension specialists received treatment with angiotensin converting enzyme (ACE)-inhibitors or angiotensin II receptor blockers (ARBs) and calcium channel blockers (CCBs) but a smaller percentage received standard beta-blockers (Table 2).

## Discussion

The major new finding in this post-hoc analysis is that under-treatment of hypertension in primary care markedly limited the ability of the barber-based BP monitoring and medical referral program to lower systolic BP. The findings indicate that intervention potency could be improved by an order of magnitude if new care delivery and payment models would enable barbers to refer all their hypertensive patrons to specialty-trained providers.

The intervention model emphasized the barber-patron relationship, with the only direct link between the referring barbers and medical providers being referral cards, which showed that systolic BP in the barbershop was on average  $\sim 20$  mmHg above recommended treatment targets. However, we found that the cards alone are not sufficient to influence provider prescribing behavior, because BP reduction—as well as the numbers and classes of BP medications prescribed—in intervention-arm patrons treated by PCPs were indistinguishable from those in comparison-arm patrons treated by PCPs. These findings are consistent with recent analysis of the National Ambulatory Medical Care Survey showing that office-based PCPs prescribe new BP medication for patients with an established diagnosis of

hypertension during only one in five office visits where the recorded systolic BP is >140 mmHg.<sup>13</sup>

The involvement of hypertension specialists in the intervention was not pre-specified but rather evolved as the only viable means to offer affordable hypertension treatment to a subset of participants who were too young to qualify for Medicare and were employed with income levels that both were too high to qualify for Medicaid or standard safety-net care but too low to afford private health insurance, high deductibles, and copayments. The 21 mmHg larger reduction in systolic BP (and 13 mmHg larger reduction in diastolic BP) in this intervention subgroup (vs. the comparison group) represents the optimal situation of the barber-based BP monitoring and medical referral program being linked directly to affordable specialty-level healthcare.

The effect size is impressive for two reasons. First, this intervention subgroup had less favorable baseline demographics—a decade younger in age, half the duration of barbershop patronage, much less previous engagement with the healthcare system and a 7 mmHg higher baseline systolic BP—than the comparison group. Second, the comparison group itself had a sizeable BP reduction which was expected from regression to the mean,<sup>20</sup> the Hawthorne effect,<sup>21</sup> and a positive influence on treatment-seeking behavior from pamphlets on hypertension in blacks, written results of baseline BPs, and detailed instructions for appropriate medical follow.

The greater BP reduction and lower achieved BP levels in the specialist-treated patrons are explained in part by a greater percentage receiving combination drug therapy with three or more BP medications of different classes, as endorsed by recent hypertension guidelines.<sup>22–24</sup> Despite the greater number of medications prescribed by the specialists, there was no group difference in medication adherence. Specialists prescribed more ACE-inhibitors, ARBs, and CCBs, which are generally well tolerated, and avoided standard beta blockers which are less well tolerated.<sup>25</sup> Also, vasodilating beta blockers and aldosterone antagonists, which are recommended for difficult hypertension,<sup>26</sup> were prescribed only by the specialists. Their achieved average BP of 122/75 mmHg may or may not seem lower than necessary in light of recent controversy as to whether or not higher cardiovascular risk of black hypertensives justifies lower-than-usual BP treatment targets (e.g., <130/80 mmHg).<sup>15, 16</sup> Nonetheless, the final average systolic BP achieved in the comparison group fails to meet the universally accepted target for out-of-office BP <135 mmHg.<sup>23, 24</sup> Their final hypertension control rate closely approximates the currently estimated hypertension control rate for U.S. black men of 36%, which is far below that of the general population and thus considered unacceptable.<sup>2</sup>

This study has several limitations. Only a small subset of barbershop patrons completed both the baseline and exit interviews in the BARBER-1 trial, which was designed as a cohort of barbershops rather than of individuals.<sup>14</sup> Without knowing reasons why subjects did not participate in either the baseline interview or the exit interview (e.g., natural turnover of the barbershops' clientele), the analysis makes the assumption that data are missing at random. Moreover, because patrons with systolic BP <140 mmHg were excluded from this post-hoc analysis, the remaining sample size per shop was too small to retain clustered statistics. Thus, our analyses ignore intra-class correlation (ICC), which might lead us to over-estimate treatment effects;<sup>27</sup> however, the main conclusion of our study should not be affected given the robust effect size and the near-zero ICC values previously reported.<sup>8</sup> Because assignment to hypertension specialist- or PCP- treatment within the intervention group was neither random nor pre-specified, the results are hypothesis generating.



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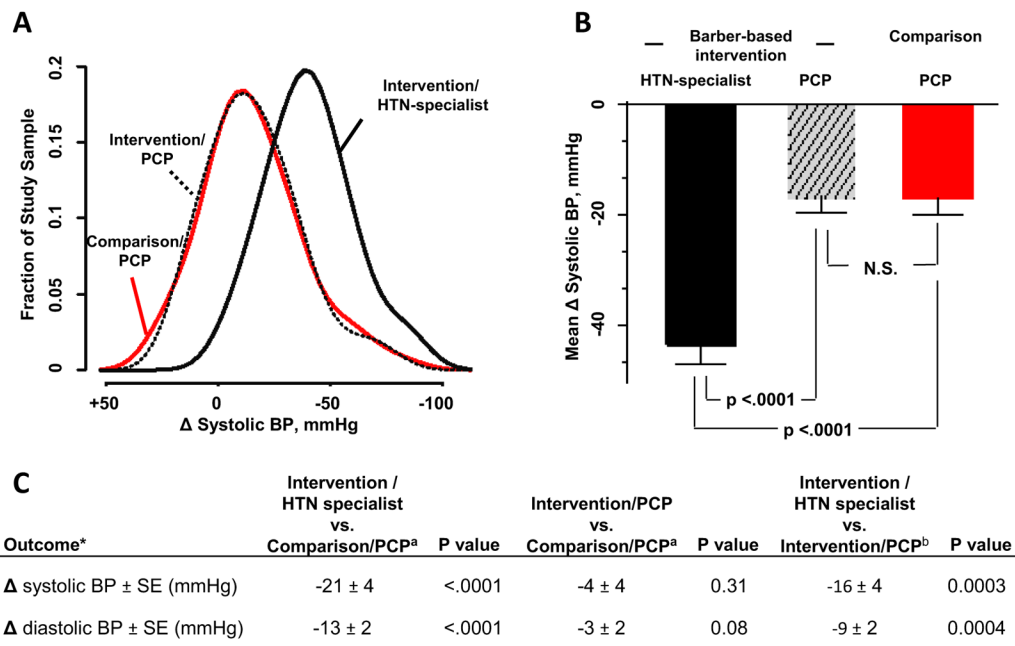
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<sup>a</sup>Linear regression model adjusted for initial BP, age, smoking status, married status, and education.

<sup>b</sup>Linear regression model adjusted for initial BP, age, smoking status, married status, education and number of medical office visits

### Figure 1. Post-hoc Analyses of BP Outcomes

A) Distribution of systolic BP change in 3 subgroups: 1) comparison group patrons treated by PCPs (red solid line); 2) intervention group patrons treated by PCPs (black dotted line); 3) intervention group patrons treated by hypertension specialists (black solid line). B) Mean change in systolic BP in the three subgroups. C) Results of the multivariate linear regression model showing adjusted estimates of the mean group differences in the change of systolic and diastolic BP. The change scores in each intervention subgroup are compared to those of the comparison group and finally within the intervention group with each other. Abbreviations: BP indicates blood pressure; HTN, hypertension; PCP, primary care provider; SE, standard error.

**Table 1**

## Baseline characteristics

Group Assignment	Barber-based Intervention		Comparison
	Treating Physicians	Hypertension-specialists	PCPs
	(n=33 patrons)	(n=37 patrons)	(n=68 patrons)
	Mean ± SE	Mean ± SE or	Mean ± SE or
Age (years)	52 ± 2*	57 ± 2	60 ± 2
Body mass index (kg•m <sup>-2</sup> )	33 ± 1	31 ± 1	32 ± 1
Married or living with partner	21 (64%)	26 (70%)	54 (80%)
Level of education			
High school	15 (46%)	20 (54%)	23 (34%)
College	16 (49%)	16 (43%)	31 (46%)
Postgraduate	2 (6%)	1 (3%)*	13 (19%)
Full-time employment	26 (79%)*	18 (49%)	33 (49%)
Any health insurance	19 (58%)*	34 (92%)	64 (94%)
Established PCP	17 (51%)*	33 (90%)	63 (93%)
Income (% of Poverty Level) <sup>a</sup>	330 ± 37	330 ± 31	380 ± 22
Barbershop patronage			
Duration (years)	8 ± 1*	7 ± 1*	13 ± 9
Time between haircuts (weeks)	3 ± 0.5	3 ± 0.5	3 ± 2
Baseline systolic BP (mmHg)	162 ± 3*	154 ± 2	155 ± 2
Baseline diastolic BP (mmHg)	96 ± 2*	88 ± 2	86 ± 1
Current smoker	8 (24%)	8 (22%)	15 (22%)
Diabetes mellitus	7 (21%)	13 (35%)	21 (37%)
Hyperlipidemia	18 (56%)*	20 (54%)	33 (49%)
History of stroke, myocardial infarction or heart failure	4 (12%)	13 (35%)*	7 (10%)

\* Likelihood ratio test p value .05 vs. comparison group

<sup>a</sup> Calculated as income/2007 United States poverty level: \$10210 for a single person and \$20650 for a 4-person household x100.

Abbreviations: BP, blood pressure; HTN, hypertension; PCP, primary care providers, SE, standard error

Table 2

## Outcomes

Group Assignment	Barber-based Intervention		Comparison
	Hypertension-specialists	PCPs	PCPs
Treating Physicians	(n=33 patrons)	(n=37 patrons)	(n=68 patrons)
Variable	Mean ± SE	Mean ± SE	Mean ± SE
<b>Final Blood Pressure</b>			
Systolic BP [mmHg]	122 ± 2 *	138 ± 3	139 ± 2
Diastolic BP [mmHg]	75 ± 1 *	81 ± 2	80 ± 1
Change of systolic BP (final-initial) [mmHg]	-41 ± 4 *	-16 ± 3	-16 ± 3
Change of diastolic BP (final-initial) [mmHg]	-21 ± 3 *	-7.4 ± 1	-6.2 ± 1
Hypertension control rate (% with final BP <135/85 mmHg) <sup>a</sup>	29 (88%) *	18 (49%)	29 (43%)
<b>Final BP regimen</b>			
<b>Number of medications</b>			
None	0 *	4 (11%)	15 (22%)
1	3 (9%)	5 (14%)	9 (13%)
2	6 (18%)	12 (32%)	19 (28%)
3 or more	24 (73%) *	16 (43%)	25 (37%)
Mean	3.4 ± 0.3 *	2.3 ± 0.2	2.1 ± 0.2
<b>Medications</b>			
ACE-inhibitor or ARBs	31 (94%) *	17 (51%)	24 (45%)
Calcium channel blocker	30 (91%) *	24 (65%)	24 (45%)
Diuretic	22 (67%)	25 (76%)	25 (47%)
Alpha/Beta blocker	11 (33%) *	2 (6%)	2 (4%)
Aldosterone antagonist	5 (20%) *	0	0
Central sympatholytic	4 (15%)	0	0
Direct vasodilator	1 (3%)	1 (3%)	1 (2%)
Beta blocker	0 *	10 (30%)	10 (19%)
Alpha blocker	0	3 (9%)	3 (6%)
<b>Medication adherence<sup>b</sup></b>	3.0 ± 0.2	3.1 ± 0.2	3.4 ± 0.2

Abbreviations: ACE indicates angiotensin converting enzyme; ARBs, angiotensin receptor blockers; BP, blood pressure; PCP, primary care providers; SE, standard error.

\* Likelihood ratio test p value <.05 vs. comparison group.

<sup>a</sup> Cut-off for out-of-office BP

<sup>b</sup> Morisky scale: scores ranging from 0 to 4, with 4 representing perfect adherence.