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Assessment of Achieved Systolic Blood Pressure in Newly Treated Hypertensive Patients Aged 60-79 Years Before and After Eighth Joint National Committee Recommendations

Assessment of achieved systolic blood pressure in newly treated hypertensive patients aged 60-79 years before and after JNC 8

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Abstract:

Objective: To determine whether patients newly prescribed antihypertensive therapy after the JNC 8 update were treated to a relaxed SBP goal compared to patients treated before the update.

Methods: Retrospective cohort study approved by Colorado Multiple Institutional Review Board. Patients aged 60-79 years, without diabetes or chronic kidney disease, newly treated for hypertension at a University of Colorado primary care clinic were included. Mean first-achieved and last-stable SBP of patients newly prescribed antihypertensive medications from January 1, 2012 to December 31, 2013 (before cohort) were compared to patients newly prescribed antihypertensive therapy from January 1, 2014 to October 1, 2015 (after cohort). Mean number of antihypertensive medications at first-achieved SBP, time to first-achieved SBP, and class of initial antihypertensive medications were also evaluated.

Results: A total of 128 patients were included, 64 patients in each cohort. The co-primary outcome of first-achieved mean SBP did not differ between groups (131.3 vs 130.2 mm Hg; p=0.65). Last-stable mean SBP values were also similar between groups (130.2 vs 129.5 mm Hg; p=0.74). Within both cohorts, angiotensin converting enzyme inhibitors were the most frequently initiated antihypertensive agents (43.8% vs 48.4%; p=0.72).

Conclusions: Our findings suggest that the JNC 8 recommendations did not alter SBP goals among patients aged 60-79 years newly treated for hypertension at University of Colorado primary care clinics.

Keywords: Hypertension, JNC 8, blood pressure goal, elderly

Introduction:
Hypertension, a major modifiable risk factor for cardiovascular disease (CVD), stroke, and chronic kidney disease (CKD), affects nearly one-third of U.S. adults aged 20 years and older (Mozaffarian et al. 2016). The prevalence of hypertension increases with age, with 65% of patients aged ≥ 60 years meeting diagnostic criteria for hypertension (Mozaffarian et al. 2016). Although a greater percentage of patients aged ≥ 60 years have controlled hypertension (blood pressure < 140/90 mm Hg) compared to younger patients, the number of older patients with hypertension that have controlled blood pressure (BP) remains suboptimal at 54.1% (Mozaffarian et al. 2016).

In 2014, two U.S. hypertension guidelines were published. The American Society of Hypertension and the International Society of Hypertension (ASH/ISH), and a report from the panel members appointed to the Eighth Joint National Committee (JNC 8)(Weber et al. 2014; James et al. 2014). Both of these guidance documents provided recommendations on BP thresholds for initiating antihypertensive treatment, preferred initial pharmacologic options, and goal BP values in specific patient populations (Weber et al. 2014);(James et al. 2014). While both recommended a relaxed systolic blood pressure (SBP) goal of < 150 mm Hg in elderly patients, they recommended different ages at which the SBP goal should be relaxed. The updated JNC 8 report recommended a SBP target of < 150 mm Hg in adults aged ≥ 60 years, without diabetes or CKD. This recommendation was given a Grade A recommendation, using a grading system developed by the National Heart, Lung, and Blood Institute's Evidence-Based Methodology Lead (James et al. 2014). Although graded as a strong recommendation, the age at which to relax the SBP goal differs from several other hypertension guidelines that recommend relaxing the SBP goal to < 150 mm Hg for patients aged ≥ 80 years (Daskalopoulou et al. 2015; Mancia et al. 2013; Weber et al. 2014).

Several experts, including a minority of JNC 8 panel members, expressed concern that evidence supporting the relaxed SBP target is insufficient (Krakoff et al. 2014);(Wright et al. 2014). Moreover, the relaxed SBP target may lead to under treatment of high-risk patients. Additionally, several registry analyses have compared the proportion of patients meeting blood pressure targets as recommended by JNC 8 and previous JNC 7 recommendations. These analyses found that 6.8-11.6% of adults aged ≥ 60 years without diabetes or CKD would be reclassified as meeting blood pressure targets by relaxing the SBP goal of < 150 mm Hg (Borden et al. 2014; Navar-Boggan et al. 2014; Miedema et al. 2015). Given the controversy surrounding the relaxed SBP goal in patients aged ≥ 60 years, and several other hypertension guidelines recommending a relaxed SBP goal starting at age 80, the objective of this study was to determine whether patients newly prescribed antihypertensive therapy after the JNC 8 report were treated to a relaxed SBP compared to patients newly treated before the JNC 8 report.

Methods:

Study design – This retrospective cohort study compared the SBP values of patients newly prescribed antihypertensive therapy for a new diagnosis of hypertension in one of seven University of Colorado Health (UCH) primary care clinics. These seven clinics included family medicine and internal medicine clinics, three of which are medical resident training sites, and most have clinical pharmacy services. Two primary endpoints were used as surrogate markers of SBP goal between cohorts; mean first-achieved SBP and mean last-stable SBP. First-achieved SBP was defined as the SBP value, obtained during a primary care clinic visit in which hypertension disease state was assessed after prescribing antihypertensive therapy, and no modifications were made to antihypertensive treatment plan. Last-stable SBP was defined as the most recent in-office SBP reading, where hypertension was assessed, and no modifications were made to antihypertensive treatment plan. SBP values recorded during clinic visits where hypertension was not assessed (i.e. acute illness visits) were not included. Secondary endpoints included time to first-achieved SBP, number of antihypertensive medications to reach first-achieved SBP, class of antihypertensive medication initiated, and number of medications at last-stable SBP.

Patient population – Patients aged 60 to 79 years with newly prescribed treatment for hypertension during the study period of January 1, 2012 to October 1, 2015 were eligible for this study. Additional inclusion criteria included a new diagnosis of hypertension (ICD-9 code 401.x) and at least one additional visit to the primary care clinic after being prescribed antihypertensive therapy, where hypertension was assessed and no changes were made to patients' antihypertensive regimen. Exclusion criteria included a diagnosis of diabetes mellitus (ICD-9 code 250.x), CKD (ICD-9 code 585.x), or kidney transplant (ICD-9 code V42.0). Patients receiving antihypertensive therapy for indications other than hypertension (i.e. atrial fibrillation, benign prostate hypertrophy, edema) prior to new hypertension diagnosis were also excluded. A list of potentially eligible patients was generated from our electronic health record (EHR) based on study criteria.

Potentially eligible patients were assigned to one of two cohorts (Figure 1). The before JNC 8 group consisted of patients newly prescribed antihypertensive therapy during the period of January 1, 2012 to December 31, 2013, while patients newly prescribed antihypertensive therapy during the period of January 1, 2014 to October 1, 2015 comprised the after JNC 8 group. The cohort time periods were chosen to provide an approximately equal time frame, and to allow time for the JNC 8 report to be disseminated to primary care providers. The online JNC 8 report was first available beginning December 18, 2013. January 1, 2014 was chosen as the initial date for the after JNC cohort, believing that enough time had passed since online publication for providers to be aware of the JNC 8 recommendations.

Patients in each cohort were randomly sorted, then EHRs were manually reviewed to ascertain if patient met criteria. The following patient data were extracted and collected for analysis: age, gender, ethnicity/race, current tobacco use, date of newly prescribed antihypertensive agent, initial in-clinic SBP, antihypertensive agent prescribed, unique number of antihypertensive medications at primary care visits, dates at which BP is assessed in clinic visit and no changes made to antihypertensive regimen, and SBP on eligible dates.

Statistical analysis– Primary and secondary continuous endpoints were compared between cohorts using unpaired t-test with Microsoft Excel. Categorical data were analyzed using two-tailed chi-square or Fisher's exact tests, calculated with GraphPad Software (http://graphpad.com/quickcalcs/contingency2/). A sample size calculation (http://clincalc.com/Stats/SampleSize.aspx) determined that a total of 128 patients (64 per group) would be necessary to provide 80% power (α=0.05) to detect a clinically significant 6 mm Hg SBP difference (standard deviation 12 mm Hg) between groups, similar to the BP parameters reported in the VALISH study (Ogihara et al. 2010). Patient EHRs were reviewed until a total of 64 patients meeting inclusion criteria in each cohort were identified. This study received expedited approval by Colorado Multiple Institutional Review Board.

Results – Of the 671 patients reviewed, 128 patients met study criteria (Figure 2). Most patients (67.2%) were excluded for having a previous diagnosis of hypertension at their initial visit when establishing care at one of the primary care clinics. Baseline characteristics were similar between groups (Table 1), including a majority of non-Hispanic white patients, mean age of 66 years, and low prevalence of tobacco use. Patients with known CVD were excluded from this study population, as they would have likely been receiving one or more antihypertensive agents as recommended by CVD guidelines (Fihn et al. 2012). Patients in both cohorts had a similar initial SBP, which trended higher in the after JNC 8 group, but was not statistically different (153.7 mm Hg vs 157.7 mm Hg; p = 0.07).

The co-primary endpoint (Table 2) of mean first-achieved SBP did not differ significantly between groups (131.3 vs 130.2 mm Hg; p = 0.65). Additionally, no statistical difference in the second co-primary endpoint of mean last-stable SBP (Table 2) was found between study groups (130.2 vs 129.5 mm Hg; p = 0.74).

Table 3 reports the frequencies of each antihypertensive agent prescribed as initial therapy. Angiotensin converting enzyme inhibitors (ACE-I) were the most frequently prescribed initial antihypertensive agent in both the before and after cohorts, 43.8% vs 48.4%, respectively (p = 0.72). Calcium channel blockers or thiazides were initiated as initial antihypertensive therapy in non-Hispanic black patients at a similar frequency in both the before and after cohorts, 57.1% vs 60.0%, respectively (p = 1.0).

DISCUSSION:
This retrospective study of patients aged 60-79 years newly prescribed antihypertensive treatment found no difference in our primary endpoints of first-achieved SBP and last-stable SBP among patients treated before and after the JNC 8 report. Both cohorts reached a mean SBP of approximately 130 mm Hg with minimal antihypertensive medications (mean 1.2 antihypertensive agents). This suggested a high degree of goal attainment, regardless of the BP goal value selected. Both cohorts demonstrated a considerable reduction in SBP (-22.4 mm Hg in the before JNC 8 cohort and -27.5 mm Hg in the after JNC 8 cohort), easily meeting SBP goal of < 140 mm Hg and < 150 mm Hg. The JNC 8 report recommended that antihypertensive treatment need not be modified if patients achieve a SBP below < 140 mm Hg and have no adverse effects associated with antihypertensive treatment (Grade E - expert opinion) (James et al. 2014). Thus, in patients with a SBP goal of < 150 mm Hg who achieved a SBP less than 140 mm Hg, modification of antihypertensive therapy would not be necessary unless they experienced adverse effects. Patients in both cohorts achieved and maintained well-controlled SBP values that did not appear to be associated with adverse effects that would require modifications to antihypertensive therapy.

Our results suggest that patients included in our study may have been treated to a more intense SBP goal than recommended by the JNC 8 report. Recently, the Systolic Blood Pressure Intervention Trial (SPRINT) found that targeting a more intensive SBP goal (< 120 mm Hg) compared to standard SBP (< 140 mm Hg) in patients with CVD risk factors resulted in a significantly lower rate of major CVD events and all-cause mortality (Anon 2015). Our study population did differ from patients included in SPRINT in many ways. First, our study population did not include patients with CKD and known CVD, while the SPRINT trial included a high percentage of patients with CKD (28%) and known CVD (20%). Additionally, most patients in the SPRINT trial (> 90%) were receiving antihypertensive treatment at baseline with a mean SBP of 140 mm Hg. Our patient population included patients with newly diagnosed, untreated hypertension with low CVD risk. Recently, a subgroup analysis of patients aged ≥ 75 years from the SPRINT trial reported a >30% reduction in all-cause mortality and the primary composite endpoint of major cardiovascular events in the group treated to intensive SBP goal < 120 mm Hg compared to SBP < 140 mm Hg (Williamson et al. 2016). Given evidence from the SPRINT trials, the JNC 8 recommendation to target SBP < 150 mm Hg seems inappropriate.

A previous study conducted at the same academic health system found no difference in mean BP and number of antihypertensive agents between a similar cohort of patients aged 60-79 years, treated for hypertension 1-year before and 1-year after the JNC 8 report (Fixen et al. 2016). Of note, patients in the previous study had an existing diagnosis of hypertension and were currently receiving antihypertensive therapy. Additionally, most patients (86%) were included in both the before and after cohort. Our current study excluded patients with a prior diagnosis of hypertension and those currently receiving antihypertensive medications. Additionally, our study design did not permit patients to be included

in both the before and after cohorts. Therefore, our results are a better measure of how the JNC 8 report has influenced primary care providers in treating hypertension in an elderly population.

One possible explanation for the substantial reduction in SBP seen in both cohorts may be due to the health status of the patients studied. Patients in our study had a mean age of 66 years, which is younger than patients studied in previous isolated systolic hypertension trials (mean age range 70-84 years) (Anon 1991; Staessen et al. 1997; Beckett et al. 2008; JATOS Study Group 2008; Ogihara et al. 2010). Our patients had few comorbidities as our exclusion criteria did not include patients with diabetes or CKD, and patients with known CVD receiving recommended medical therapy would have been excluded. Of the five trials reviewed by the JNC 8 members that included patients aged ≥ 60 years, four trials included patients (range 7% to 13.7%) with diabetes mellitus (Anon 1991; Beckett et al. 2008; JATOS Study Group 2008; Ogihara et al. 2010). The Syst-Eur trial did not report the percentage of patients with diabetes, but did report that nearly 30% of included patients had a history of cardiovascular complications at baseline (Staessen et al. 1997).

It is possible that a portion of our study patients may not have had true hypertension, but instead presented with white-coat hypertension (WCH). It is estimated that up to 30% of patients with elevated in-clinic BP values may have WCH (Siu & U.S. Preventive Services Task Force 2015). In 2015, the U.S. Preventive Services Task Force released recommendations to confirm the diagnosis of hypertension with the use of out-of-clinic BP values (Siu & U.S. Preventive Services Task Force 2015). A recent subgroup analysis examined the prevalence of WCH in patients with in-clinic HTN (BP ≥ 140/90 mm Hg) who also underwent 24-hour ambulatory blood pressure monitoring (ABPM) (Tanner et al. 2016). In the subset of patients without diabetes or CKD, patients aged ≥ 60 years had a significantly greater in office SBP compared to patients aged < 60 years (149.9 mm Hg vs 140.9 mm Hg, respectively; $p < 0.001$), but similar SBP measured by ABPM (134.8 mm Hg vs 132.2 mm Hg; $p = 0.22$). The prevalence of patients in our study with WHC cannot be determined given the retrospective study design.

Both ASH/ISH guidelines and the JNC 8 report recommend one of four classes of antihypertensive agents as initial therapy in non-Hispanic black patients. Our study found that ACE-I were the most frequently prescribed initial agent in both cohorts and also noted several other trends in prescribed initial antihypertensive therapy. First, the frequency of beta-blockers as initial therapy in the before JNC 8 cohort trended down in the after JNC 8 cohort (6.3% vs 3.1%; p=0.68), which is in line with recommendations against the use of beta-blocking agents as first-line antihypertensive agents.(Weber et al. 2014; James et al. 2014) Second, we found an increased frequency of angiotensin receptor blockers (ARBs) use as initial therapy from 7.8% in the before cohort to 10.9% in the after cohort (p=0.76). This trend may be explained by the fact that several ARBs became

available as generic products after the release of JNC 8. Due to ASH/ISH and JNC 8 recommendations specifying initial antihypertensive therapy in non-Hispanic black patients, a pre-specified subgroup analysis was conducted to determine if more non-Hispanic black patients in the after JNC 8 cohort were initially prescribed a calcium channel blocker (CCB) or thiazide compared to non-Hispanic black patients in the before JNC 8 cohort. A total of 12 non-Hispanic black patients were included in the patient sample, (seven in the before cohort and five in the after cohort) with no statistical difference between groups. A future study including only non-Hispanic black patients may be useful to determine if initial antihypertensive therapy follows the recommendations from both U.S. hypertension guidelines (Weber et al. 2014; James et al. 2014).

There are several limitations of this study, most notably our retrospective design. First, medication adherence could not be assessed due to our study design, which may have falsely increased our secondary endpoint of time to first-achieved SBP. In a study assessing adherence to antihypertensive medications among patients newly treated for hypertension, less than 10% of subjects had an adherence rate ≥ 80% (portion of days covered) at 6 months (Mazzaglia et al. 2009). Secondly, we can not ensure that BP was measured using the recommended technique described by hypertension guidelines (Weber et al. 2014). A third limitation of this study is our use of surrogate endpoints to evaluate SBP goals, since BP goals were not consistently documented in the EHR. Although we limited our assessment to only SBP values during clinic visits assessing patients' hypertension disease state, patients who achieved a SBP below their goal value without adverse effects would be recommended to continue current antihypertensive therapy, based upon the JNC 8 corollary recommendation (James et al. 2014). Lastly, our study included a limited number of primary care clinics, all of which are affiliated with a single academic health system and have clinical pharmacy services available. Several clinics have collaborative drug therapy management (CDTM) protocols, which allow pharmacists to manage and modify patients' antihypertensive therapy in collaboration with primary care providers. Whether the availability of clinical pharmacy services influenced the SBP goal of patients included in this study cannot be determined. Future studies comparing the achieved SBP values for patients initiating antihypertensive treatment in primary clinics affiliated with an academic health center compared to primary care clinics not affiliated with academic health centers may be of value.

Conclusion

Our findings did not identify a change in overall intensity of BP lowering among patients with newly diagnosed hypertension. Our findings were limited to patients aged 60 to 79 years, without CKD or diabetes, receiving care from primary care providers of an academic health system. Overall, treatment of this population does not appear to have been negatively influenced by the JNC 8 recommendations to relax the SBP goal among these patients.

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Table 1: Patient demographics of before and after cohorts at baseline			
Characteristic	**Before JNC 8 (n=64)**	**After JNC 8 (n=64)**	**P value**
Mean age in years (SD)	65.8 (4.9)	66.2 (4.6)	0.33
Female sex (%)	64.1	64.1	1.00
Race/Ethnic group (%)			???
Non-Hispanic white	79.7	78.1	
Non-Hispanic black	10.9	7.8	
Hispanic	3.1	4.7	
Other	6.3	9.4	
Current Tobacco use (%)	17.2	9.4	0.30
Initial mean SBP in mm Hg (SD)	153.7 (11.0)	157.7 (13.3)	0.07
Initial mean DBP in mm Hg (SD)	87.0 (9.5)	89.2 (8.6)	0.16
DBP= diastolic blood pressure; JNC 8= Eighth Joint National Committee; SBP= systolic blood pressure; SD = standard deviation.			

Table 2: Results of primary endpoints			
	Before JNC 8 (n=64)	**After JNC 8 (n=64)**	**P value**
First-achieved SBP (mm Hg)	131.3 ± 13.6	130.2 ± 11.7	0.65
First-achieved DBP (mm Hg)	76.6 ± 10.2	79.0 ± 8.4	0.15
Last-stable SBP (mm Hg)	130.2 ± 12.2	129.5 ± 11.8	0.74
Last-stable DBP (mm Hg)	78.1 ± 7.2	77.2 ± 8.6	0.53
*Plus-minus values are mean ± standard deviation; DBP= diastolic blood pressure; JNC 8= Eighth Joint National Committee; SBP= systolic blood pressure.			

Table 3: Results of secondary endpoints			
	Before JNC 8 (n=64)	**After JNC 8 (n=64)**	**P value**
Time to first-achieved SBP (days)	83.7	77.1	0.65
Medications to reach first-achieved SBP (no.)	1.23	1.17	0.41
Medications at last-stable SBP (no.)	1.16	1.25	0.33
Class of medication initiated (%)			0.50
ACE-I	43.8	48.4	0.72
ARB	7.8	10.9	0.76
CCB	12.5	10.9	1.00
Thiazide	26.6	15.6	0.19
Beta-blocker	6.2	3.1	0.68
Aldosterone antagonist	0.00	1.6	1.00
Combination medication			
ACE-I/HCTZ	3.1	7.8	0.21
ARB/HCTZ	0.0	1.6	1.00
ACE-I= angiotensin converting enzyme inhibitor; ARB= angiotensin receptor blocker; CCB= calcium channel blocker; HCTZ= hydrochlorothiazide; JNC 8= Eighth Joint National Committee; No.= number; SBP= systolic blood pressure.			

Figure 1: Study cohorts by date

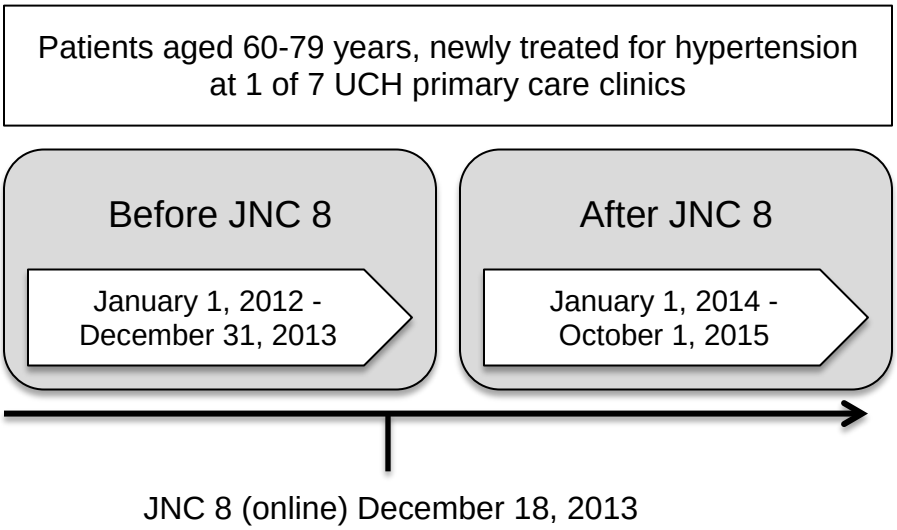
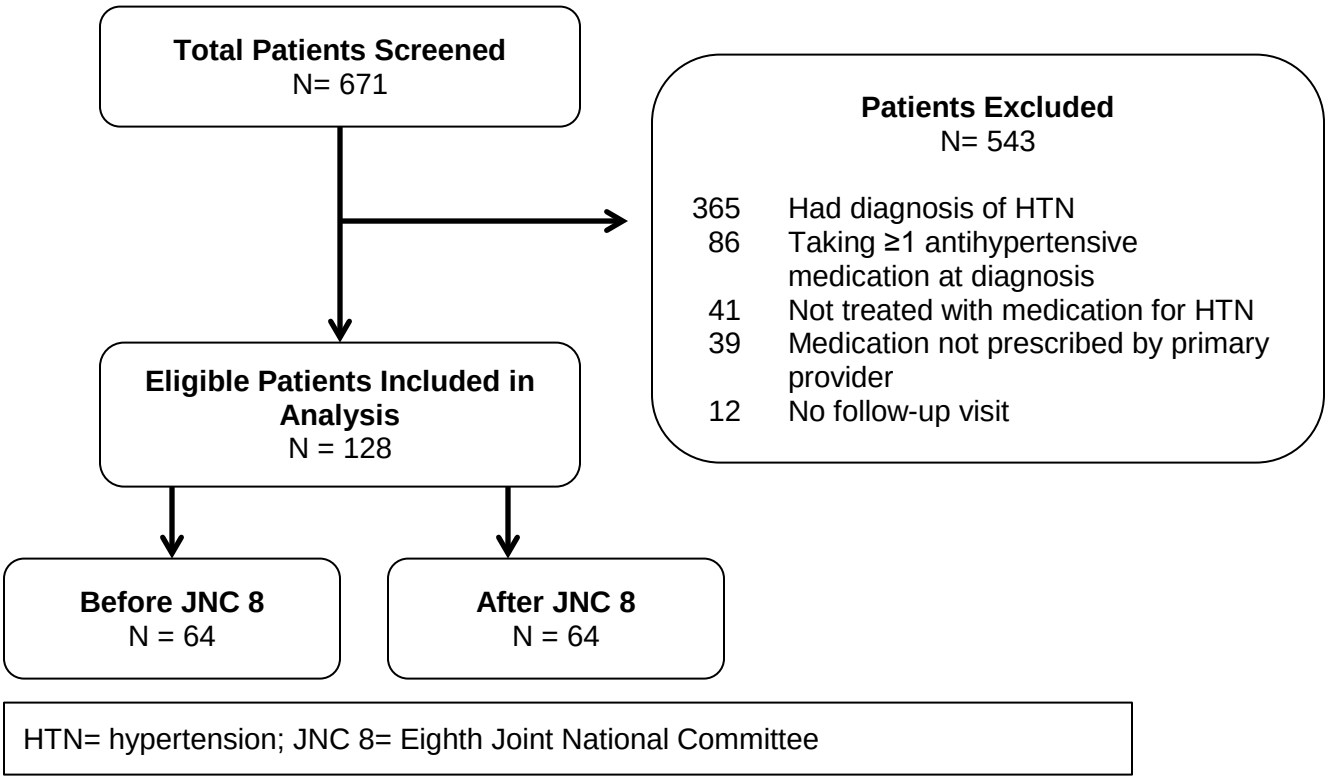


Figure 2: Patients screened and included in analysis.



HTN= hypertension; JNC 8= Eighth Joint National Committee