

Antihypertensive Medication Persistence 1-Year Post-Stroke Hospitalization

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To optimize the translation of clinical trial evidence that antihypertensive treatment reduces recurrent stroke risk into clinical practice, it is important to assess the frequency of long-term antihypertensive drug persistence after stroke and identify the factors associated with low persistence. Structured telephone interviews to determine antihypertensive regimen persistence 1-year post-stroke hospitalization were conducted in 270 stroke survivors, of which 212 (78.5%) were discharged on antihypertensive therapy (two thirds on >1 drug class). Continued use of any antihypertensive agent at 1 year of follow-up was relatively high (87.3%); however, persistence on all or two or more drug classes prescribed at discharge was relatively low (38.7%). Continued use varied by drug class, with the highest rates among angiotensin-

converting enzyme inhibitor (69.1%) and the lowest rates among diuretic (24.4%) users. Black patients (adjusted odds ratio, 0.35; 95% confidence interval, 0.16–0.78) and those with a high comorbidity burden (adjusted odds ratio, 0.39; 95% confidence interval, 0.18–0.86) were less likely to exhibit persistence on prescribed treatments 1-year post-stroke hospitalization. These results indicate the need for further study to identify appropriate persistence of antihypertensive therapies for secondary stroke prevention and to investigate reasons for racial disparities in persistence on prescribed treatments in a real-world clinical setting *J Clin Hypertens (Greenwich)*. 2014;16:869–874. © 2014 Wiley Periodicals, Inc.

Blood pressure (BP) is recognized as an important modifiable risk factor for stroke in both hypertensive and nonhypertensive patients.¹ As much as 50% of strokes may be attributable to exposure to high BP.² Hypertension also poses a major risk for recurrent stroke and will continue to do so if the lifetime risk of elevated BP remains unattenuated.^{2–4} Current guidelines have incorporated hypertension treatment to reduce recurrent stroke risk.^{1,3} However, growing evidence from a number of registries in varying countries suggest that BP remains poorly controlled with relatively poor persistence with antihypertensive treatment in a considerable number of patients in the post-stroke discharge setting, which may contribute to increased recurrent stroke incidence, hospital readmissions, and death after stroke.^{4–7} Studies suggest that in-hospital initiation of antihypertensive therapies prior to stroke discharge may improve treatment utilization,⁸ adherence,^{9,10} and risk of recurrent vascular events.^{11,12} While clinical trial evidence indicates the benefits of hypertension treatment to reduce recurrent stroke risk, to optimize this evidence into clinical practice, it is important to assess the frequency of long-term antihypertensive drug persistence after stroke and identify the factors associated

with low persistence. The purpose of this study was to assess differential patterns of antihypertensive regimens prescribed at discharge and persistent use at 1 year among stroke survivors in a real-world clinical setting.

METHODS

Study Population

Stroke survivors, aged 45 years and older, discharged from the Medical University of South Carolina (MUSC) Stroke Services from October 1, 2008, to September 30, 2009, were identified. Structured telephone interviews were used to determine patient persistence on stroke prevention discharge medications 1-year post-stroke hospitalization. The survey tool was adapted from a standardized post-hospitalization questionnaire, written in lay terms, and beta-tested on patients whose data were not included in the analysis. The telephone interviews were conducted in English by trained research interview professionals from a contracted research facility. Deceased patients and those residing in a full-time care facility in which medication use is regulated were excluded from the study. Family members or primary caregiver proxies were allowed for patients who could not respond because of illness severity or speech or language deficits; however, the patient had to provide verbal consent for the proxy to complete the interview on their behalf. Patients were considered lost to follow-up after several unsuccessful call attempts were made or the patient/proxy declined participation. Among the 779 patients assessed for eligibility, 16.7% died prior to follow-up interview,

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4.5% resided in a full-time care facility, and 30.0% were unreachable or declined participation. A total of 381 patients verbally consented to the telephone interview, with 270 completing the medication questionnaire. This study was approved by the MUSC institutional review board.

Study Measures

Information on demographics, clinical outcomes, and discharge variables including discharge medications and last reported BP measurement prior to discharge were obtained from the patients' electronic medical records and were then matched to the state inpatient hospitalization discharge database provided by the South Carolina Office of Research and Statistics.

Comorbid conditions were based on secondary discharge diagnoses and were classified using the Modified Charlson Index (MCI) score dichotomized as low comorbidity burden (index 0 or 1) vs high comorbidity burden (index ≥ 2).¹³ Stroke hospitalizations within 1 year prior to the study period were considered the index stroke. Recurrent stroke was defined as a second primary stroke discharge of >1 day but within 1 year of the index stroke. For patients with multiple stroke hospitalizations during the study period, the latest hospitalization records were used and we assumed all answers to the questionnaire were in response to their most recent stroke hospitalization at the time of the telephone interview.

Medication continuation was ascertained by comparing medications prescribed at hospital discharge with the current medications reported by the patient/proxy. Medication use prior to stroke hospitalization (premorbid treatment) and modifications post-stroke were assessed. Antilipidemic medications were classified as statins and nonstatins, and antithrombotic medications were classified as antiplatelets and anticoagulants. Classes of antihypertensive medications were categorized as diuretics, β -blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers (CCBs), and "others." Persistence was defined as continuation on all or at least two medications based on drug class prescribed at hospital discharge.

Univariate regression, chi-square test for categorical variables, and Mann-Whitney *U*-test for continuous variables was used to compare baseline characteristics associated with prescription of antihypertensive therapy at discharge. Logistic regression was used to assess the independent associations of patient characteristics with persistence on all or at least two discharged antihypertensive medications based on drug class at time of follow-up. Variables with $P < .25$ in univariate analysis were included in multivariate analysis with additional adjustments for prespecified covariates of age, sex, insurance coverage, stroke type, and premorbid antihypertensive therapy, and post-hoc for proxy interview responders to control for any influence a caregiver may have on level of medication persistence based on the

assumption that patients requiring proxies to complete the interview on their behalf most likely have a caregiver administering their medications. A subset analysis of self-responders excluding the proxy interviews was evaluated. Adjusted odds ratios (AORs) and 95% confidence intervals (CIs) were calculated. SAS version 9.4 (SAS Institute Inc, Cary, NC) was used for all statistical analyses.

RESULTS

A total of 270 stroke survivors were included in the analyses, of whom 60 (22.2%) were black and 110 (40.7%) were men, with an average age of 64.9 ± 11.3 years. Among black patients, 42 (70.0%) were aged 45 to 64 years, compared with 92 years (43.8%) among white patients. Ischemic stroke accounted for 47.0% of the hospitalizations. Sixty-four percent of the patients were diagnosed with comorbid hypertension and 38.2% were discharged with a BP $\geq 140/90$ mm Hg.

Of the 270 stroke survivors, 212 (78.5%) were discharged on antihypertensive therapy. Baseline characteristics associated with antihypertensive therapy prescribed at discharge are shown in Table I. Older patients (aged ≥ 65 years), men, and patients with comorbid hypertension, diabetes, dyslipidemia, or heart disease were more likely to be discharged on antihypertensive therapy. There was no difference in length of hospital stay, having some type of insurance coverage, or discharge disposition between patients discharged on antihypertensive therapy vs those not on therapy. However, a significantly higher proportion of patients not discharged on antihypertensive therapy had a current history of smoking. Patients prescribed statin or antiplatelet therapy were more likely to be discharged on antihypertensive therapy and patients with premorbid use of antihypertensive medications were more likely to be continued on therapy.

β -Blockers (41.5%) and ACE inhibitors (40.7%) were the most prescribed class of antihypertensives among the cohort (Table II) and were the most common regimens used in combination (39.3% among those discharged on two or more drug classes). Among patients discharged on antihypertensive therapy, 87.3% remained on some antihypertensive regimen at follow-up. Continued use varied by antihypertensive drug class, with highest rates among ACE inhibitor users (69.1%) and lowest rates among diuretic users (24.4%). Among patients who reported premorbid use of antihypertensive therapy, 42.4% claimed that the physician altered the dosage, class, or brand of their antihypertensive medication after stroke hospitalization. Of the 58 patients not discharged on an antihypertensive, 25.9% were started on an antihypertensive regimen prior to follow-up (16% on an ACE inhibitor), whereas 74% never had therapy initiated after hospital discharge.

While reasons for medication changes could not be assessed, we found that among those classified as nonpersistent, 12.7% of patients dropped all antihypertensive regimens at the time of follow-up, 7.1% changed

TABLE I. Antihypertensive Therapy Prescribed at Discharge (N=270)

Characteristics	On Antihypertensive (n=212)	Not on Antihypertensive (n=58)	P Value ^a
Black race	49 (23.1)	11 (19.0)	.501
Age ≥65 y	118 (55.7)	18 (31.0)	<.001
Male	94 (44.3)	16 (27.6)	.021
Stroke type			
Ischemic	112 (52.8)	15 (25.9)	<.001
Hemorrhagic	50 (23.6)	19 (32.8)	.156
TIA	13 (6.1)	3 (5.2)	.784
Other	37 (14.5)	21 (36.2)	.002
SBP at discharge, mm Hg	135.7±21.7	123.7±20.3	<.001
DBP at discharge, mm Hg	71.4±13.5	68.7±13.9	.210
BP ≥140/90 mm Hg	91 (42.9)	12 (20.7)	.002
Comorbidities			
Hypertension	155 (73.1)	19 (32.8)	<.001
Diabetes	52 (24.5)	4 (6.9)	.003
Dyslipidemia	99 (46.7)	18 (31.0)	.033
Heart disease	41 (19.3)	3 (5.2)	.010
Atrial fibrillation	25 (11.8)	5 (8.6)	.496
High comorbidity burden (MCI ≥2)	46 (21.7)	1 (1.7)	<.001
Prior stroke	46 (21.7)	18 (31.0)	.139
1-y recurrent stroke	34 (16.0)	12 (20.7)	.404
Body mass index >30 kg/m ²	71 (34.6)	12 (22.2)	.082
Current smoking	73 (34.4)	34 (58.6)	<.001
Length of hospital stay	5.2±7.3	5.7±5.7	.254
Had insurance coverage			
Private	69 (32.6)	29 (50.0)	.014
Medicare	118 (55.7)	24 (41.4)	.054
Medicaid	13 (6.1)	2 (3.5)	.429
Self-pay	12 (5.7)	3 (5.2)	.886
Discharged home/with home services	162 (76.4)	50 (86.2)	.108
Discharge medication ^b			
Antilipidemic	167 (78.8)	30 (51.7)	<.001
Statin	162 (76.4)	30 (51.7)	<.001
Nonstatin	40 (18.9)	5 (8.6)	.064
Antithrombotic	158 (74.5)	29 (50.0)	<.001
Antiplatelet	140 (66.0)	24 (41.4)	<.001
Anticoagulant	39 (18.4)	8 (13.8)	.413
Antihypertensive therapy			
Premorbid use	151 (71.2)	7 (12.1)	<.001
On at follow-up	185 (87.3)	15 (25.9)	<.001

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; MCI, Modified Charlson Index; SBP, systolic blood pressure; SD, standard deviation; TIA, transient ischemic attack. Values are presented as number (percentage) or mean±standard deviation. ^aP value of chi-square test for categorical variables and Mann-Whitney U-test for continuous variables. ^bSome patients were discharged on >1 drug per drug type and class.

TABLE II. Prevention Medication Persistence by Drug Class

Drug Class	Prescription at Discharge, No. (%) (N=270)	Continued Use at Follow-Up, No. (%)	Persistence, ^a No. (%)
Antihypertensive	212 (78.5)	185 (87.3)	82 (38.7)
Diuretic	82 (30.4)	20 (24.4)	
β-Blocker	112 (41.5)	41 (36.6)	
CCB	67 (24.8)	32 (47.8)	
ACE inhibitor	110 (40.7)	76 (69.1)	
ARB	40 (14.8)	19 (47.5)	
Other	16 (5.9)	6 (37.5)	
Antilipidemic	197 (73.0)	160 (81.2)	126 (64.0)
Statin	192 (71.1)	151 (78.7)	
Nonstatin	45 (16.7)	13 (28.9)	
Antithrombotic	187 (69.3)	166 (88.8)	149 (79.7)
Antiplatelet	164 (60.7)	143 (87.2)	
Anticoagulant	47 (17.4)	28 (59.6)	
Combination use			
Antihypertensive and antilipidemic	167 (61.9)	121 (72.46)	44 (26.4)
Antihypertensive and antithrombotic	158 (58.5)	122 (77.2)	51 (32.3)
Antihypertensive, antilipidemic, and antithrombotic	134 (49.6)	94 (70.2)	37 (27.6)

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CCB, calcium channel blocker. ^aPersistence at time of follow-up was defined as continuation on all or at least two medications based on drug class prescribed at hospital discharge.

the classes of antihypertensives but remained on the same number of medications as they were discharged on, 39.2% changed >50% of the discharge regimen to remain on one antihypertensive at follow-up, and 1.4% remained on two antihypertensive classes at follow-up, while only 0.9% (two patients) actually increased the number of antihypertensive medications by the time of follow-up. Among those who were classified as persistent, 74.4% remained on the exact regimen prescribed at discharge, 7.3% remained on the discharge regimen but had additional drugs added to their regimen at follow-up, and the remaining 18.3% decreased the total number of current medications but remained on at least two of the drug classes prescribed at discharge.

The rate of some continual medication use was slightly lower for antilipidemic therapy (81.2%; 78.7% statins, 28.9% non-statins), but similar for antithrombotic therapy (88.8%; 87.2% antiplatelets, 59.6% anticoagulants) as compared with continued antihypertensive use at follow-up. Of patients not prescribed antilipidemic or antithrombotic therapy at discharge, 27.4% were started on a statin regimen and 31.1% on an aspirin regimen prior to the follow-up survey. The rate of persistence on medication regimens within the same drug class prescribed at hospital

discharge was 64.0% for antilipidemics and 79.7% for antithrombotics, whereas the rate of persistent use for antihypertensives was only 38.7%. Black patients (AOR, 0.34; 95% CI, 0.15–0.76) and patients with a high comorbidity burden (AOR, 0.38; 95% CI, 0.18–0.84) were significantly less likely to be persistent on their discharged antihypertensive regimen at 1-year follow-up, even after adjusting for age, sex, insurance coverage, stroke type, premorbid antihypertensive therapy, and proxy interview responders (Table III). Persistence on antilipidemics or antithrombotics was not

independently associated with patient characteristics (data not shown). Subset analysis of persistence among self-responders (168, 80% of the cohort) showed similar results, with black patients (AOR, 0.36; 95% CI, 0.14–0.82) and those with a high comorbidity burden (AOR, 0.32; 95% CI, 0.12–0.83) significantly less likely to be persistent on their antihypertensive regimen after adjustments.

DISCUSSION

In this cohort, nearly 80% of stroke survivors were discharged on at least one antihypertensive medication, with a majority (66%) discharged on two or more agents. While the proportion of stroke survivors who remained on some antihypertensive regimen at follow-up was relatively high (>80%), persistence on the specific antihypertensive treatment prescribed at discharge was relatively low (<40%). Older patients, patients with stroke-related comorbidities, and patients with premorbid use of antihypertensive therapy were more likely to be prescribed an antihypertensive regimen at discharge. Contraindications and other barriers to initiating a medication regimen at time of discharge may have contributed to the lack of prescribed antihypertensive therapy; however, inadequate length of stay to initiate hypertension management, lack of insurance coverage, or advanced end-organ diseases were not associated with prescribed therapy at discharge. In addition, all patients not prescribed antihypertensives received other medications at discharge, with >50% receiving statins. Further analysis on a case-by-case basis is needed to assess the justifications for not initiating antihypertensive therapy in stroke patients at discharge.

In-hospital initiation of antihypertensive therapies post-stroke significantly improves hospital discharge treatment utilization⁸ and medication adherence^{9,10} within the months following stroke hospitalization, in addition to reducing the risk of recurrent vascular events.^{11,12} “Sentinel hospitalization” is a unique opportunity to institute evidence-based prevention strategies during the acute stroke hospitalization; otherwise, long-term initiation of treatment may be deferred to the post-discharge clinical setting in which there is a risk of loss of adequate follow-up of care and reduced medication persistence.^{9,10}

Therapy regimens are critical considerations in the assessment of medication persistence. The Perindopril Protection Against Recurrent Stroke Study (PROGRESS)¹⁴ found that an ACE inhibitor–based BP-lowering regimen in combination with a thiazide-type diuretic produced larger BP and recurrent stroke risk reductions than monotherapy in both hypertensive and normotensive patients. However, it should be noted that in our study only 18% of stroke survivors were discharged on a combination of an ACE inhibitor and diuretic. Individuals with an increased risk as indicated with a prior history of stroke may be treated differently based on their medical history.³ However, in this study,

TABLE III. Characteristics Associated With Antihypertensive Medication Persistence (n=212)

Characteristics	No.	Persistence, ^a No. (%)	Univariate P Value	Adjusted ^b OR (95% CI); P Value
Race				
White	163	70 (42.9)		Reference
Black	49	12 (24.5)	.022	0.34 (0.15–0.76); <.009
Age, y				
45–65	94	37 (39.4)		
≥65	118	45 (38.1)	.855	
Sex				
Female	118	47 (39.8)		
Male	94	35 (37.2)	.700	
BP ≥140/90 mm Hg				
No	121	45 (37.2)		
Yes	91	37 (40.7)	.608	
Comorbidity burden				
Low (MCI 0–1)	166	71 (42.8)		Reference
High (MCI ≥2)	46	11 (23.9)	.023	0.38 (0.18–0.84); <.016
Prior stroke				
No	166	65 (39.2)		
Yes	46	17 (37.0)	.786	
1-y recurrent stroke				
No	178	66 (37.1)		
Yes	34	16 (47.1)	.276	
Insurance coverage				
Private	69	30 (43.5)		
Medicare	118	39 (33.1)		
Medicaid	13	7 (53.9)		
Self-pay	12	6 (50.0)		
Premorbid antihypertensive use				
No	61	21 (34.4)		
Yes	151	61 (40.4)	.420	
Prescribed FDC				
No	175	69 (39.4)		
Yes	37	13 (35.1)	.626	

Abbreviations: BP, blood pressure; CI, confidence interval; FDC, fixed-dose combination; MCI, Modified Charlson Index; OR, odds ratio. ^aPersistence at time of follow-up was defined as continuation on all or at least two antihypertensive medications based on drug class prescribed at hospital discharge. ^bAdjusted for age, sex, insurance coverage, stroke type, premorbid antihypertensive therapy, and proxy interview responders.

a history of prior stroke was not associated with prescribed antihypertensive regimen at discharge, despite the current guidelines suggesting antihypertensive use in secondary stroke prevention, even among normotensive patients.^{1,3}

The rate of continued use of any antihypertensive therapy was consistent with other studies among stroke patients.¹⁰ However, the persistence rates for specific drug class regimens were substantially lower than other assessments.^{10,15,16} The Preventing Recurrence of Thromboembolic Events Through Coordinated Treatment (PROTECT)¹⁰ study reported high rates of continued use of ACE inhibitors/ARBs (89%) and thiazide diuretics (82%) at 1-year follow-up; these rates are considerably higher than the 71% for ACE inhibitors/ARBs and 24% for diuretics in the current study. The higher rates reported in the PROTECT study may be affected by the intense structure of a controlled clinical trial that incorporated strategies to enhance adherence.¹⁰ Sappok and colleagues¹⁵ reported a higher rate of absolute persistence (56%) on all antihypertensive discharge regimens at 1-year post-stroke among a German cohort of patients discharged on antithrombotic therapy. Similarly, the Adherence Evaluation After Ischemic Stroke—Longitudinal (AVAIL) Registry¹⁶ study reported significantly higher rates of absolute persistence (66%) on antihypertensives by drug class at 1 year in patients hospitalized in American Heart Association/American Stroke Association Get With The Guidelines—Stroke hospitals, whereas antihypertensive regimen persistence in our study was <40%. The AVAIL study completed an interview assessment 3 months following stroke discharge and patients consented to be contacted again at the 12-month time point; thus, patients' awareness of the future interview and content of the interview may have influenced their level of persistence on discharge regimens given that they knew they would be re-interviewed in 9 months, whereas patients in our study were not aware that they would be contacted for a follow-up assessment post-discharge, thus potentially accounting for the significant differences in the estimated rates of persistence. While persistence on specific drug class regimens found in this study varied significantly from other reports among stroke patients, the rates were similar to those reported among a general cohort of antihypertensive drug users, with significantly higher rates of persistence at 1 year among ARB and ACE inhibitor users as compared with diuretic users, despite the relatively low cost of diuretic therapy.¹⁷ Thus, the choice of initial antihypertensive drug class may have an impact on medication persistence.

In this study, patients with lower rates of persistence at 1-year post-stroke hospitalization included blacks and stroke survivors with comorbid conditions. The racial differences in therapy persistence could be caused, in part, by socioeconomic factors.¹⁸ While these indicators were not assessed in detail in this study, the majority (96%) of patients had some type of insurance

coverage, and type of coverage was not associated with medication persistence. Higher comorbidity burden was inversely associated with persistence, which may be associated with additional medications, increased costs, and increased rates of contraindications for aggressive antihypertensive therapy. Simplified medication regimens, such as fixed-dose combination medications, have been shown to increase adherence;¹⁹ however, fixed-dose combination therapy was not significantly associated with persistence in our study. The AVAIL study found that the most common reason for nonpersistence was the discontinuation of therapy based on the recommendations of their post-discharge healthcare provider.¹⁶ Frequent contact with a physician may contribute to an increase in changes made to the patient's therapeutic regimen as a result of nonadherence or adverse effects of the medication, and thus decrease persistence on discharged regimens. In our study, however, having a post-stroke follow-up appointment at the hospital outpatient clinic or seeing a primary care provider on a regular basis did not significantly increase the level of persistence on the antihypertensive regimen prescribed at discharge (data not shown).

When comparing other secondary stroke prevention therapies, continuance on any antilipidemic at 1-year post-discharge was slightly lower than for antihypertensive therapy but was similar for antithrombotic therapy. However, these rates are substantially lower than the rates reported in the Ovbiagele¹⁰ and Lummis²⁰ and colleagues studies, where rates of continued use at 1 year was 99% and 91% for antilipidemics and 98% and 96% for antithrombotics, respectively.

STUDY STRENGTHS AND LIMITATIONS

The strengths of our study are that it represents an assessment of prescribed antihypertensive treatment regimens and real-life assessments of persistence in a relatively young (mean age, 65 years) high-risk population from a clinical setting. Most studies involving secondary stroke prevention medication adherence and persistence are based on national registries^{6,16} or well-controlled clinical trials,^{10,21} for which data are less generalizable and thus may overestimate medication persistence. Our method of measuring persistence was limited to patient/proxy self-report data; however, no gold standard has been established to measure medication persistence and studies have shown sufficient agreement between patient self-report data and pharmacy claims records.^{20,22} In addition, reasons for discontinuation of medication such as potential contraindications or adverse effects, which may have been physician-, as opposed to patient-, initiated, were not assessed in this study. Patients who died or were unreachable by telephone were not included in the follow-up assessment and thus may result in overestimates of persistence. While the proportion of black patients in this study was representative of the racial profile of eligible stroke survivors (~30%), the survey

response rate of black patients was considerably lower than white patients (52% vs 67%, respectively) and thus may be underrepresented in this study. This could be caused, in part, by the fact that black patients were discharged to another type of full-time care facility at a significantly higher rate as compared with white patients and thus may not have been reachable by telephone at follow-up. Medications listed at last stroke hospitalization during the study period were used to compare with the follow-up medication list; thus, potential medication changes during nonstroke readmissions were not assessed. Finally, we did not collect information on BP throughout the hospital stay, which may have affected the prescribed therapies, especially since studies have shown that BP within days of acute stroke may not reflect the patients' baseline levels.²³ In addition, BP was not assessed at time of follow-up interview; therefore, changes in antihypertensive regimen could be caused by effective BP control; however, guidelines suggest that antihypertensive therapy is beneficial in all stroke survivors as a means of secondary prevention regardless of hypertension status prior to stroke hospitalization.¹

CONCLUSIONS

Long-term persistence on some antihypertensive regimens in this cohort was relatively high (>80%); however, persistence on specific drug class treatment regimens prescribed at discharge was relatively low (<40%). Continued use varied considerably by drug class. Black patients and patients with high comorbidity burden were less likely to exhibit persistence on prescribed treatments 1-year post-stroke hospitalization. These results indicate the need for further study to identify appropriate persistence of antihypertensive therapies for secondary stroke prevention and to investigate reasons for racial disparities in persistence on prescribed treatments in a real-world clinical setting.

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