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# Hypertension Treatment and Concern About Falling: Baseline Data from the Systolic Blood Pressure Intervention Trial

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## Abstract

**OBJECTIVES:** To determine the extent of concern about falling in older adults with hypertension, whether lower blood pressure (BP) and greater use of antihypertensive medications are associated with greater concern about falling, and whether lower BP has a greater effect on concern about falling in older and more functionally impaired individuals.

**DESIGN:** Secondary analysis involving cross-sectional study of baseline characteristics of participants enrolled in the Systolic Blood Pressure Intervention Trial (SPRINT).

**SETTING:** Approximately 100 outpatient sites.

**PARTICIPANTS:** SPRINT enrollees aged 50 and older (mean age 69) diagnosed with hypertension (N = 2,299).

**MEASUREMENTS:** Concern about falling was determined using the shortened version of the Falls Efficacy Scale International as measured at the baseline examination.

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**RESULTS:** Mild concern about falling was present in 29.3% of participants and moderate to severe concern in 17.9%. Neither low BP (systolic BP<120 mmHg, diastolic BP <70 mmHg) nor orthostatic hypotension was associated with concern about falling ($P > .10$). Participants with moderate to severe concern about falling were taking significantly more antihypertensive medications than those with mild or no concern. After adjusting for baseline characteristics, no associations were evident between BP, medications, and concern about falling. Results were similar in older and younger participants; interactions between BP and age and functional status were not significantly associated with concern about falling.

**CONCLUSION:** Although concern about falling is common in older adults with hypertension, it was not found to be associated with low BP or use of more antihypertensive medications in baseline data from SPRINT.

### Keywords

hypertension; falls; concern about falling

Management of hypertension in older adults requires careful balancing of the benefits and risks of therapy.[1] Intensification of antihypertensive therapy to achieve guideline-recommended thresholds reduces the incidence of cardiovascular morbidity and mortality, although conflicting study results have suggested that this therapy might increase the risk of side effects, including falls and fall-related injuries.[2,3] When faced with this uncertainty, nearly 50% of elderly adults with hypertension preferred not to intensify antihypertensive therapy because of concerns about fall-related injuries and other medication-related adverse effects.[4] This suggests that understanding concern about falling separately from actual falls may be important in individuals undergoing treatment for hypertension. Knowledge about whether lower blood pressure (BP) and greater use of antihypertensive medications are associated with greater concern about falling may assist in discussions with older adults with hypertension about appropriate management that balances benefits, risks, and preferences for treatment.

Concern about falling is highly prevalent in community dwelling elderly adults, with prevalence rates of up to 85% depending on the population and instrument used.[5] Factors associated with concern about falling include older age, nonwhite race, higher body mass index (BMI), and poorer functional status,[5,6] yet little is known about concern about falling in older adults with hypertension. Baseline data from the Systolic Blood Pressure Intervention Trial (SPRINT) were used to explore this issue.[7] Specifically, the answers to three questions were examined: What is the extent of concern about falling in older adults undergoing treatment for hypertension? Is lower BP and greater use of antihypertensive medications associated with greater concern about falling? Do lower BP and greater medication use have a greater effect on concern about falling in older and more functionally impaired individuals?

## METHODS

Study methods for SPRINT have been described elsewhere.[7] Briefly, it is a multicenter randomized controlled trial comparing two strategies for managing systolic BP (SBP) in

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older adults with hypertension: a standard care strategy targeting SBP of less than 140 mmHg and an intensive strategy with a SBP target of less than 120 mmHg. The primary outcome is the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular disease. The target population of SPRINT was individuals aged 50 and older with SBP measured at a screening visit of 130–180 mmHg. Participants taking antihypertensive medications were not excluded. Participants were required to be at risk of the outcomes listed above as evidenced by clinical or subclinical cardiovascular disease, chronic kidney disease, high Framingham risk score, or aged 75 and older. Individuals with diabetes mellitus or prior stroke were excluded. Enrollment began in November 2010 and ended in March 2013 with the recruitment of 9,361 individuals from approximately 100 outpatient sites. Each site's institutional review board approved the study, which was registered with clincaltrials.gov (NCT01206062).

The present study is a secondary analysis based on a subsample of the full SPRINT population selected to receive additional health-related quality-of-life assessments to capture various dimensions of function, including concern about falling. All data, including concern about falling, are from the baseline assessment and do not incorporate data from follow-up assessments. Information on prior falls was not determined at baseline.

The dependent variable in the analyses was concern about falling as measured using the short version of the Falls Efficacy Scale International (FES-I).[8] This version of the FES-I [9] consists of seven items, which the respondent answers on a scale from 1 (not at all concerned) to 4 (very concerned), indicating level of concern about falling in performing a particular activity. Activities assessed are dressing or undressing, taking a bath or shower, getting in or out of a chair, going up or down stairs, reaching for something above the head or on the ground, walking up or down a slope, and going out to a social event. An evaluation of the short FES-I found good internal and 4-week test-retest reliability.[8] Scores range from 7 to 28, with higher scores indicating greater concern about falling.

Other data used in these analyses were collected as part of the baseline assessment. Demographic data included sex, age, and race and ethnicity. Physical examination findings included BP and BMI. BP was assessed after a 5-minute rest period using an automated device in a sitting and standing position. Orthostatic hypotension was defined as a 20-mmHg drop in SBP or a 10-mmHg drop in diastolic BP (DBP). Dizziness on standing for BP measurement was determined according to self-report. All antihypertensive medications being taken were recorded. Health-related quality-of-life was assessed using the Veterans Rand 12-item questionnaire (VR-12).[10] Physical and mental health composite scores on the VR-12 range from 0 to 100, with lower scores indicating worse function and a score of 50 representing the U.S. population mean. Presence of depressive symptoms was measured using the Patient Health Questionnaire (PHQ-9).[11] Cognition was assessed using the Montreal Cognitive Assessment (MoCA).[12] Self-reported comorbidities were captured using the Selim Index, which sums the presence of 30 physical and six mental health conditions.[13] Medication adherence was measured using the Morisky Medication Adherence Scale (low adherence vs medium to high adherence).[14]

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### Analyses

Consistent with other studies, a short FES-I score of 11 or less was considered to indicate moderate to severe concern about falling,[6] and a score of 8–10 was considered to indicate mild concern about falling. In examining the association between BP and concern about falling, SBP and DBP from the baseline visit were used as continuous variables and dichotomous variables of low versus not low. Different thresholds were considered to maximize the potential of demonstrating an association between low BP and greater concern about falling. Specific thresholds examined were SBP of 140, 120, or 100 mmHg and DBP of 90, 80, or 70 mmHg. Whether there were differences in concern about falling between participants above and below each threshold was determined. A composite measurement of low BP requiring SBP less than 120 and DBP less than 70 was also considered.

Descriptive statistics with means and standard deviations for continuous measures and frequency distributions for categorical variables were reported according to FES-I category (none, mild, moderate to severe). Associations between BP and concern about falling and between number of antihypertensive medications and concern about falling were examined using chi-square or Fisher exact tests for dichotomous variables and analysis of variance for continuous measures.

Multivariate ordinal logistic regression was performed to examine the independent association between BP and concern about falling and between number of antihypertensive medications and concern about falling. Adjusted odds ratios and 95% confidence intervals were estimated. Factors shown to be associated with concern about falling in past studies or in bivariate testing (sex, age, race and ethnicity, BMI, VR-12 physical and mental component scores, number of physical comorbidities, number of mental comorbidities, PHQ-9 score, and MoCA score) were adjusted for. Because results were similar with the different definitions of low BP, only the multivariate model that included orthostatic hypotension, SBP less than 120 mmHg, and DBP less than 70 mmHg is reported. Four interaction terms (low BP and age, low BP and VR-12 physical score, number of antihypertensive medications and age, number of antihypertensive medications and VR-12 physical score) were examined to determine whether low BP or number of medications was associated with greater concern about falling in older and more functionally impaired participants. The Score Test for the Proportional Odds Assumption was nonsignificant, indicating that the ordinal logistic model was appropriate. A twosided $P < .05$ was considered statistically significant. Analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC).

## RESULTS

Information on concern about falling was collected on 2,299 individuals with hypertension of the 9,361 SPRINT participants. Baseline characteristics are described in Table 1. Participants had a mean age of 69.0 ± 10.3, 66.9% were male, and 58.6% were non-Hispanic white. They had a mean 4.5 ± 2.8 physical comorbidities, and mean VR-12 physical score was 44.8 ± 10.1. One thousand two hundred fourteen participants (52.8%) reported no concern about falling, 674 (29.3%) reported mild concern, and 411 (17.9%) reported moderate to severe concern.

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There were no differences in baseline SBP or DBP between participants with no, mild, or moderate to severe concern about falling (Table 2). Similarly, the proportion of people with low BP was similar in the three groups when considering the different definitions of low BP. Orthostatic hypotension was present in 6.6% of people with no concern about falling, 9.2% of those with mild concern, and 7.6% of those with moderate to severe concern ($P = .11$). Self-reported dizziness on standing was more common in those with moderate to severe concern about falling (7.8%) than in those with no (2.9%) or mild (4.2%) concern about falling ($P < .001$). More than 90% of participants were taking antihypertensive medications at the baseline visit; being on medication was associated with greater concern about falling ($P = .03$). People with moderate to severe concern about falling were taking a mean of 2.0 antihypertensive medications, and those with no or mild concern about falling were taking a mean of 1.8 ($P < .001$). Results were similar in older (≥75) and younger (<75) participants.

In multivariate analyses, a number of baseline characteristics were associated with greater concern about falling, including older age, female sex, higher BMI, worse physical and mental function on the VR-12, and worse symptoms of depression on the PHQ-9. Non-Hispanic white participants had less concern about falling. Neither low BP nor number of antihypertensive medications was a significant predictor of concern about falling (Table 3). The interactions between low BP and age, low BP and VR-12 physical function, number of antihypertensive medications and age, and number of antihypertensive medications and VR-12 physical function were not significant.

## DISCUSSION

Concern about falling, also known as falls self-efficacy and fear of falling, contributes to poor psychological health and less social activity in older adults.[5,15] Although concern about falling has been studied in community-dwelling elderly adults,[5,16] people who have fallen,[5,8] and people with specific conditions such as pain,[17] there is limited information on concern about falling in individuals with hypertension. Developing a better understanding of concern about falling in individuals with hypertension is particularly important given the uncertainty regarding the association between intensification of BP treatment and falling,[1–3] as well as the ongoing debate concerning appropriate treatment targets for elderly adults with hypertension.[18] Delivery of person-centered hypertension care will require careful discussions between clinicians and patients to determine appropriate treatment goals.

These results highlight several important findings. First, concern about falling is prevalent, with 47.2% reporting some concern; 17.9% had moderate to severe concern. Studies of concern about falling in community-dwelling elderly adults have reported widely differing rates, with estimates ranging from 3% to 85%.[5] Many of these studies were small, but several large European studies have demonstrated rates similar to those of the current study. Of more than 4,000 Dutch community-dwelling elderly adults aged 70 and older, 54.3% were concerned about falling.[16] Moderate to severe concern about falling was present in 19% of a sample of more than 1,000 English elderly adults,[6] similar to the 17.9% in the current study. A nationally representative sample of elderly adults from the U.S. National Health and Aging Trends Study reported that 37% with bothersome pain and 16% without pain were worried about falling.[17] Whether concern about falling is more prevalent in older

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adults with hypertension than in the broader population of community-dwelling elderly adults cannot be determined from the results of the current study.

Although concern about falling is prevalent in individuals with hypertension, the current study found no evidence that it is related to low BP. Different definitions of low BP, including BP as a continuous variable, dichotomizing BP at various thresholds, and considering only orthostatic hypotension were considered, but no association was found with bivariate or multivariate testing. Taking more antihypertensive medications was associated with greater concern about falling in bivariate testing but not after adjusting for other baseline characteristics. Given the cross-sectional design of this study, it is possible that this lack of association may be because participants who developed concern about falling decreased their medications. Prospective data would be needed to address this issue.

No evidence was found of a greater effect of low BP on concern about falling in older and more-impaired individuals with hypertension. Results were similar when the analyses were limited to participants aged 75 and older. Interactions between low BP with age and between low BP and VR-12 scores were also examined, and no association was found. Care must be taken in generalizing these results to older and severely functionally impaired individuals with hypertension who may not be well represented in the SPRINT population.

There is little reason to question the validity of these results. SPRINT followed rigorous protocols in collection of data.[7] The instruments used, including the FES-I,[8,9] have been evaluated extensively for their reliability and validity. Moreover, the results of the multivariate analyses, such as for nonwhite ethnicity, older age, higher BMI, worse health-related quality of life, and depressive symptomatology being associated with greater concern about falling, have been noted elsewhere.[5,6]

Several limitations of this study should be noted. Concern about falling was addressed because it could be an important consideration in people’s willingness to intensify therapy for hypertension, although it is likely that elderly adults with hypertension have broader concerns about medication side effects that affect their decisions. Furthermore, the short FES-I may be more sensitive in detecting balance difficulties in elderly adults than orthostatic symptoms arising from low BP. Cross-sectional data from the baseline assessment in SPRINT were used. Information on a prior history of falls was not available at baseline but could have been helpful in understanding concern about falling. Only number of antihypertensive medications was considered, but this may not fully capture the intensity of treatment. Concerns could be raised about the external validity of the results. Although SPRINT endeavored to enroll older adults with hypertension with comorbidities, the population recruited may not be representative of the broader population. Finally, in developing the multivariate models, assumptions were made regarding causality among the variables. It could be that greater concern about falling results in worse health-related quality of life and depressive symptomatology, although the results were unchanged when VR-12 scores were excluded from the models except that comorbidity scores became significant predictors. This suggests that low VR-12 scores reflect disease burden rather than being caused by worse concern about falling.

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Data about concern about falling and recent falls were collected as part of each SPRINT annual assessment. As these prospective data become available, it will be possible to better determine whether treatment intensification to further lower BP results in falls and worsening concern about falling. The effect of treatment-induced hypotension on these outcomes could also be determined.

Although concern about falling is common in individuals with hypertension, it does not appear to be related to lower BP or more antihypertensive medications in these baseline data from SPRINT. This information should help clinicians and individuals in reaching decisions on whether to intensify therapy to achieve guideline recommended treatment goals in older adults with hypertension.

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**Table 1.**

Baseline Characteristics of the Study Population (N = 2,299)

| Characteristic | Value |
|---|---|
| Age, mean ± SD | 69.0 ±10.3 |
| Non-Hispanic white, % | 58.6 |
| Number of physical comorbidities, mean ± SD | 4.5 ± 2.8 |
| Number of mental comorbidities, mean ± SD | 0.4 ± 0.8 |
| Veterans Rand 12-item questionnaire score, mean ± SD[a] | |
| Physical component | 44.8 ± 10.1 |
| Mental component | 53.2 ± 9.4 |
| Patient Health Questionnaire-9 score, mean ± SD[b] | 3.0 ± 4.0 |
| Body mass index, kg/m$^2$, mean ± SD | 29.6 ± 5.7 |
| Montreal Cognitive Assessment score, mean ± SD[c] | 22.6 ± 4.1 |
| Dizzy upon standing for blood pressure measurement, % | 4.1 |
| Vitamin D use, % | 19.7 |
| Alcohol use, % | |
| Nondrinker | 46.4 |
| Light drinker | 21.0 |
| Moderate to heavy drinker | 32.6 |

[a] Range 0–100; higher scores indicate better function.

[b] Range 0–27; higher scores indicate greater depressive symptoms.

[c] Range 0–30; higher scores indicate better cognitive function.

SD = standard deviation.

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**Table 2.**

Association Between Blood Pressure (BP) and Concern About Falling and Between Number of Antihypertensive Medications and Concern About Falling

| BP and Antihypertensive Medications | Overall, N = 2,299 | No Concern About Falling, n = 1,214 | Mild Concern About Falling, n = 674 | Moderate to Severe Concern About Falling, n = 411 | *P*-Value |
|---|---|---|---|---|---|
| SBP, mean ± SD | 140.3 ± 15.6 | 140.3 ± 15.5 | 140.1 ± 15.2 | 140.5 ± 16.7 | .92 |
| DBP, mean ± SD | 77.8 ± 12.0 | 78.2 ± 11.8 | 76.9 ± 12.3 | 77.8 ± 12.1 | .07 |
| SBP, mmHg, n (%) | | | | | |
| <100 | 5 (0.2) | 2 (0.2) | 1 (0.2) | 2 (0.5) | .08 |
| <120 | 185 (8.1) | 95 (7.8) | 47 (7.0) | 43 (10.5) | .11 |
| <140 | 1,187 (51.7) | 621 (51.2) | 353 (52.5) | 213 (51.8) | .87 |
| DBP, mmHg, n (%) | | | | | |
| <70 | 565 (24.6) | 280 (23.1) | 185 (27.5) | 100 (24.3) | .10 |
| <80 | 1,310 (57.0) | 674 (55.6) | 403 (59.9) | 233 (56.7) | .19 |
| <90 | 1,938 (84.4) | 1,015 (83.7) | 573 (85.1) | 350 (85.2) | .63 |
| SBP <120 mmHg and DBP <70 mmHg | 122 (5.3) | 61 (5.0) | 33 (4.9) | 28 (6.8) | .32 |
| Orthostatic hypotension | 173 (7.5) | 80 (6.6) | 62 (9.2) | 31 (7.6) | .11 |
| Taking any antihypertensive medication | 2,084 (90.7) | 1,088 (89.6) | 610 (90.5) | 386 (93.9) | .03 |
| Number taking antihypertensive medication, mean ± SD | 1.8 ± 1.0 | 1.8 ± 1.0 | 1.8 ± 1.0 | 2.0 ± 1.0 | <.001 |

SBP = systolic blood pressure; DBP = diastolic blood pressure; SD = standard deviation.

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**Table 3.**

Results of Multivariable Logistic Regression Model Examining Associations with Concern About Falling

| Characteristic | Adjusted Odds Ratio (95% Confidence Interval) | *P*-Value |
|---|---|---|
| SBP <120 mmHg | 1.22 (0.87–1.71) | .26 |
| DBP <70 mmHg | 0.87 (0.69–1.09) | .22 |
| Orthostatic hypotension | 1.06 (0.76–1.46) | .74 |
| Number of antihypertensive medications | 0.99 (0.91–1.08) | .79 |
| Female | 1.72 (1.43–2.08) | <.001 |
| Age | 1.06 (1.04–1.07) | <.001 |
| Non-Hispanic white | 0.77 (0.63–0.96) | .02 |
| Body mass index | 1.03 (1.01–1.05) | <.001 |
| Veterans Rand 12-item questionnaire score | | |
| Physical component | 0.91 (0.90–0.92) | <.001 |
| Mental component | 0.96 (0.95–0.97) | <.001 |
| Number of Physical Comorbidities | 0.99 (0.96–1.03) | .63 |
| Number of Mental Comorbidities | 1.07 (0.95–1.21) | .26 |
| Patient Health Questionnaire-9 score | 1.08 (1.04–1.12) | <.001 |
| Montreal Cognitive Assessment score | 1.00 (0.98–1.03) | .83 |

Older age, higher body mass index, and more depressive symptoms were associated with greater concern about falling.

Better physical and mental function were associated with less concern about falling.