

Low Systolic Blood Pressure From Treatment and  
Association With Serious Falls/Syncope

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**Introduction:** With the growing emphasis on intensive blood pressure control, the potential for overtreatment and treatment-related adverse outcomes has become an area of interest. A large representative population within a real-world clinical environment with successful hypertension control rates was used to evaluate serious falls and syncope in people with low-treated systolic blood pressure (SBP).

**Methods:** A cross-sectional study among medically treated hypertensive individuals within the Kaiser Permanente Southern California health system (2014–2015) was performed. Serious fall injuries and syncope were identified using ICD codes based on emergency department and hospitalization diagnoses. SBPs in a 1-year window were used to compare serious falls and syncope among individuals with SBP <110 mmHg vs  $\geq$ 110 mmHg. Logistic regression was used to evaluate the association between low minimum and mean SBP and serious falls/syncope after adjustment for demographics, comorbidities, and medications.

**Results:** In 477,516 treated hypertensive individuals, the mean age was 65 (SD=13) years and the mean SBP was 129 (SD=10) mmHg, with 27% having a minimum SBP <110 mmHg and 3% having mean SBP <110 mmHg. A total of 15,419 (3.2%) individuals experienced a serious fall or syncope or both during the observation window (5.7% among minimum SBP <110 mmHg and 5.4% among mean SBP <110 mmHg). The multivariable ORs for serious falls/syncope were 2.18 (95% CI=2.11, 2.25) for minimum SBP <110 mmHg and 1.54 (95%CI=1.43, 1.66) for mean SBP <110 mmHg compared with SBP  $\geq$ 110 mmHg.

**Conclusions:** Among treated hypertensive patients, both minimum and mean SBP less than 110 mmHg were associated with serious falls and syncope. Low treatment-related blood pressures deserve consideration given the emphasis on intensive blood pressure control.

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## INTRODUCTION

Hypertension (HTN), as defined by the American Heart Association/American College of Cardiology guideline for the prevention, detection, evaluation, and management of high blood pressure (BP) in adults, is prevalent in an estimated 46% of the general population, which represents more than 100 million adults in the U.S.<sup>1</sup> Determining the most appropriate BP goals among the HTN population has been controversial, but accumulating evidence supports more aggressive BP lowering.<sup>1–3</sup>

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With the growing emphasis on intensive BP control, the potential for overtreatment and treatment-related adverse outcomes is an important consideration. Although studies including the Systolic Blood Pressure Intervention Trial (SPRINT) have shown improved outcomes with lower BP goals, aggressive BP control does not come without substantial risk.<sup>4–10</sup> Falls, particularly in the elderly population, are a significant public health concern and lead to substantial healthcare costs.<sup>11,12</sup> Older adults have a high risk for falls, which often result in serious injuries and increased mortality.<sup>13–15</sup> Up to 30% of individuals aged more than 65 years suffer from at least one fall per year, which is even higher among those with lower BP.<sup>15–18</sup> Observations among older adults have shown that antihypertensive medication use is associated with higher risk for serious falls.<sup>11,14,19</sup> However, studies that have evaluated BP-lowering treatment (systolic BP [SBP] less than 150 mmHg) with risk for falls and syncope remain inconsistent in their findings.<sup>5,11,14,20–22</sup> In the intensively treated SPRINT cohort, including the subgroup of participants aged 75 years and older, there was an increased risk of syncope but not for injurious falls associated with targeting an SBP less than 120 mmHg versus less than 140 mmHg.<sup>4,21</sup>

Clinical trials are often composed of specialized populations screened using specific study inclusion criteria, and have careful follow-up throughout the clinical trial period, including close observation after the titration of medications. Therefore, the impact of highly successful BP treatment and its risk on adverse outcomes in a real-world clinical environment remains largely unknown. Kaiser Permanente is a large health system that has used the integrated care model, electronic health records, and a multidisciplinary approach toward the management of HTN to achieve BP control rates exceeding 85% for the past decade.<sup>23,24</sup> The large and ethnically diverse population within Kaiser Permanente Southern California (KPSC) is used in this study to evaluate the associations of low on-treatment SBP with serious falls and syncope among adults with HTN. SBP less than 110 mmHg was used to define low SBP because there has been no demonstrable benefit of having or treating BP to this level.<sup>25</sup> Studying these associations in KPSC with its comprehensive strategy for BP lowering and high rate of HTN control may provide important insights into treatment-associated adverse outcomes among patients with HTN.

## METHODS

### Study Population

This study was conducted among members of KPSC, an integrated health system providing comprehensive care

to >4.4 million members throughout Southern California at 15 medical centers and >200 satellite clinics. The patient population is racially/ethnically and socioeconomically diverse, reflecting the general population of Southern California.<sup>26–28</sup> Complete healthcare encounters were tracked using common electronic health records from which all study information was extracted. All laboratory data; vital sign assessments (including BP measurements); and diagnostic and procedure codes were collected in the electronic health records as part of routine clinical care encounters. The study protocol was reviewed and approved by the KPSC IRB and was exempt from informed consent (IRB No. 5932).

Individuals aged  $\geq 18$  years with HTN and a documented outpatient BP measurement were identified in the period between July 1, 2014, and June 30, 2015. Individuals were identified as having HTN based on diagnosis codes and antihypertensive medication use.<sup>24</sup> The first date (between July 1, 2014, and June 30, 2015) of identification of HTN was considered the “index date” for the observation window. The study observation window was the 1-year period after that index date. Individuals were required to have a minimum of one antihypertensive medication prescription that overlapped with the index date.

### Measures

Outpatient BP measurements were performed by providers (primarily medical assistants) who are certified in BP measurement at the time of hiring and retrained annually. Patients rest for 5 minutes before BP is measured. BP is measured using an automated oscillometric device. Individuals are in a seated position, back supported, and with both feet on the floor. In addition, providers are instructed to repeat BP measurements when they are too low or high (SBP <110 or >140 mmHg). BP values that were measured during an encounter in the 1-year observation window were included for analyses. When there was a single encounter with multiple BP measurements, the lowest value was used for analysis to minimize white coat hypertension and to capture acute hypotensive episodes, which may have included orthostatic hypotension.<sup>29</sup> KPSC has an internally derived and disseminated HTN algorithm that is followed by the majority of physicians (Appendix Figure 1, available online).<sup>24,28,30</sup>

Comorbidities, including HTN; diabetes mellitus; ischemic heart disease (defined as history of acute myocardial infarction); peripheral vascular disease; congestive heart failure; and dementia were assessed based on inpatient and outpatient ICD diagnoses coding.

Antihypertensive medication data were retrieved from KPSC pharmacy databases. Individuals were determined

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