Systolic Blood Pressure and Subjective Well-Being in Patients with Coronary Artery Disease

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ABSTRACT

Background: Limited information exists regarding the association between subjective well-being (SWB) and systolic blood pressure (SBP) among hypertensive patients with coronary artery disease (CAD).

Hypothesis: We tested the hypothesis that there is an association between SBP and SWB.

Methods: We studied 22576 hypertensive CAD patients ≥50 years old in the INternational VErapamil SR-Trandolapril Study (INVEST), a randomized, blinded-endpoint trial of antihypertensive therapy in stable CAD patients. At each study visit, patients rated their SWB in the previous 4 weeks as "excellent," "good," "fair," or "poor" prior to SBP recordings. The outcome measure was SWB of "fair" or "poor." A longitudinal analysis using generalized estimating equations was performed to assess the association between SBP and odds of reporting fair/poor SWB, controlling for baseline SWB of fair/poor and angina reported during the study.

Results: Patients with higher SBP had higher odds of reporting fair/poor SWB. Specifically, compared with patients with SBP of ≤120, patients with SBP >150 – ≤160 and >160 had about 90% and 2.5 times greater odds of feeling fair/poor, respectively (adjusted odds ratio [OR]: 1.90, 95% confidence interval [CI]: 1.81–2.00 and adjusted OR: 2.53, 95% CI: 2.41–2.66). Those who reported angina in the 4 weeks prior to a protocol visit had 2.2 times greater odds of reporting fair/poor SWB (adjusted OR: 2.2, 95% CI: 2.13–2.27). Female gender, black race, history of smoking, diabetes, myocardial infarction, stroke, and cancer also increased the odds of reporting fair/poor SWB.

Conclusions: Among hypertensive CAD patients, higher on-treatment SBP is associated with greater odds of fair/poor SWB during follow-up.

Introduction

The global epidemic of cardiovascular disease, principally coronary artery disease (CAD), calls for new approaches to management. The focus of therapy for CAD patients with hypertension is to reduce adverse outcomes like death, myocardial infarction or stroke. However, even in high-risk cohorts like those in the INternational VErapamil-SR Trandolapril STudy (INVEST), most patients do not experience these events in the near term. So, improving health-related quality of life (HRQOL) is an important goal. Although large number of studies on HRQOL among hypertensive patients have been reported,[1] information related to the role of blood pressure (BP) on quality of life over time in hypertensive patients with CAD is limited.[2,3]

Hypertension is a major risk condition for CAD. While there are ample data to document that lower BP is beneficial, similar data consistently show poor compliance with BP lowering treatments. If lower BP were linked with improved health-related quality of life or subjective well-being, perhaps this information could be used to help to motivate patients to improve their compliance with treatment. Accordingly, we investigated the association between HRQOL, estimated by self-reported subjective well-being (SWB), other patient characteristics present at entry, and systolic BP (SBP)

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during treatment in a large group of hypertensive CAD patients.

Methods

Patient Population

The current study is a cohort study of a previously published large hypertensive trial, INVEST. The INVEST rationale, design, inclusion and exclusion criteria, treatment strategies, and main results have been published in detail elsewhere.[4,5] INVEST was a randomized, open label, blinded endpoint study of 22576 hypertensive CAD patients age 50 years or older, conducted from September 1997 to February 2003 at 862 sites in 14 countries. Briefly, patients were eligible if they were age 50 years or older and had documented CAD with essential hypertension requiring drug therapy as defined by the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI)[6]. Documented CAD was defined as any of the following: remote (≥3 m prior to enrollment) confirmed myocardial infarction (MI), coronary angiogram with more than 50% narrowing of at least 1 major coronary artery, diagnosis of classic angina pectoris or concordant abnormalities on 2 different types of signals (electrocardiograms, echocardiograms, and/or radionuclide scans) from stress tests provided that 2 different signals showed findings consistent for ischemia (eg, ST-segment depression and/or perfusion defects by radionuclide, and/or wall-motion abnormalities by echocardiogram or radionuclide). Patients with NYHA Heart Association (NYHA) heart failure classes I through III were included. Patients New York Heart Association (NYHA) taking β-blockers within 2 weeks of randomization or taking β-blockers for an MI that occurred in the previous 12 months were excluded to avoid withdrawal phenomena in patients randomized to the calcium channel antagonist group.

These clinically stable CAD patients with hypertension were randomly assigned to either verapamil SR or atenolol for blood pressure treatment according to JNC VI (target: systolic blood pressure [SBP] <140 and diastolic blood pressure [DBP] <90 mm Hg or SBP <130 mm Hg and DBP <85 mm Hg when diabetes or renal impairment is present).[6] Addition of trandolapril and/or hydrochlorothiazide was recommended when necessary to achieve blood pressure goals. Trandolapril was also recommended for patients with heart failure, diabetes or renal insufficiency.[4]

Patients were evaluated every 6 weeks for the first 6 months and then semiannually for at least 2 years, to assess SWB, BP, and adverse outcomes. The primary outcome of interest for INVEST was the first occurrence of death, nonfatal myocardial infarction, or nonfatal stroke. The protocol was conducted in accordance with principles outlined in the Declaration of Helsinki, and institutional review boards and ethics committees at participating sites approved the protocol, and patients provided written informed consent. Data regarding medical history and demographics at baseline were recorded by site investigators on standardized forms at enrollment and at each follow-up visit.

Outcome Variable: Fair/Poor Subjective Well-Being

The INVEST protocol required completion of a validated single-item questionnaire with four response options[7] to assess self-reported SWB before determination of BP and collection of information on adverse events. The questionnaire has been shown to be associated with HRQOL and adverse clinical outcomes.[7] SWB was measured at baseline and each visit thereafter by asking patients to rate their overall feeling of well-being in the prior 4 weeks as "excellent," "good," "fair," or "poor." The outcome of interest for this analysis was an SWB report of either "fair" or "poor."

Predictor Variables

BP measurement: At each visit, following assessment of SWB, BP was measured with the patient in a seated position after a 5-minute rest period. The mean of 2 BP cuff measurements was used for the BP at each visit.

Potential confounding factors: Baseline demographic data including age, gender, self-reported race/ethnicity (White, Black, Asian, Hispanic, or other), and medical history of diabetes, angina, stroke/transient ischemic attack (TIA), revascularization (either coronary artery bypass graft or percutaneous coronary intervention), left ventricular hypertrophy, BMI, smoking history cancer, and congestive heart failure were documented by study physicians at each site. At each visit, patients were asked if they had experienced any episodes of angina in the preceding 4 weeks (as yes or no since last visit).

Statistical Analysis

The goal of this analysis was to examine the contribution of SBP to patient-reported SWB. The SBP recorded at baseline was grouped into six categories: 1 SBP ≤ 120, 2 SBP > 120 ≤ 130, 3 SBP >130 − ≤ 140, 4 SBP >140 ≤150, 5 SBP >150 − ≤160, and (6) SBP >160 mm Hg.

The analysis was performed for individual patients with each of their study visits corresponding to each follow-up time interval (in months). Potential associations between SBP and odds of reporting SWB of fair/poor were analyzed using a generalized estimating equation (GEE), adjusting for baseline characteristics such as SWB of fair/poor and other confounding factors such as age (decades), gender, race/ethnicity, prior MI, history of stroke/TIA, diabetes, BMI, smoking history, and history of cancer. Angina (yes or no) at each visit was entered in the model. SBP and angina values used were data collected at each time point. All other variables were baseline characteristics. SAS procedure PROC GENMOD (generalized linear model procedure) (SAS Institute, Cary, NC) was used to

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perform GEE with logit link and lag-1 autoregressive correlation structure. Results are reported as odds ratios (ORs) with 95% confidence intervals (CIs) of reporting fair/poor SWB for each predictor adjusted for other predictors in the model. A 2-tailed p value <0.05 was considered statistically significant. Statistical analyses were performed using SAS version 9.1.

Results

Patient Baseline Characteristics

Between 1997 and 2003, 61835 patient-years of follow-up were accumulated. Mean follow-up was 2.7 years (range, 1 d–5.4 years). The baseline characteristics, medical history, and medication information categorized by baseline SBP is listed in Table 1. Patients were elderly (mean

Table 1. Patient Characteristics[a] by SBP Category at Baseline

	Category 1 SBP (≤120 mm Hg) n = 1,305 (5.8%)	Category 2 SBP (>120 and ≤130 mm Hg) n = 2,168 (9.6%)	Category 3 SBP (>130 and ≤140 mm Hg) n = 3,829 (17.0%)	Category 4 SBP (>140 and ≤150) n = 4,803 (21.3%)	Category 5 SBP (>150 and ≤160 mm Hg) n = 4,509 (20.0%)	Category 6 SBP >160 mm Hg n = 5,962 (26.4%)	p
Age, mean (SD), y	65.7 (9.9)	65.8 (9.8)	65.8 (9.8)	66.1 (9.8)	66.0 (9.6)	66.9 (9.8)	<0.0001
Women	51.34	51.2	50.07	50.2	51.23	56.22	<0.0001
Race:							<0.0001
White	41.7	42.5	41.4	49.5	52.5	52.4	
Black	13	13	12.9	13.1	12.1	15.2	
Hispanic	42.5	41.8	43.9	35.1	32.2	29.5	
Other/multiracial	2.8	2.6	1.8	2.3	3.1	2.8	
BMI, mean (SD), kg/m^2	28.7 (5.6)	29.1 (5.5)	29.5 (8.3)	29.4 (7.5)	29.1 (5.7)	29.0 (7.6)	0.0012
Smoking History	50	45.4	45.4	46.9	47.1	45.3	0.001
Myocardial Infarction	35.2	32.1	30	32.7	33.6	30.7	0.0003
Angina Pectoris	64.1	63.9	65.6	63.7	67.9	70.2	<0.0001
Stroke/TIA	9.1	7.4	6.1	6.9	6.8	7.9	0.0013
Left Ventricular Hypertrophy	16.5	17	16.2	19.9	23.6	28.9	<0.0001
Arrhythmia	8.9	7.3	6.5	7.1	6.9	7.1	0.104
Heart Failure (NYHA class I–III)	9	6.3	4.5	5.6	5.3	5.4	<0.0001
Peripheral Vascular Disease	14.9	13.8	11.6	11.8	11	11.7	0.0003
Diabetes[b]	27.7	30.1	29.2	27.2	28.1	28.4	0.168
Hypercholesterolemia[b]	59.3	58.1	55.5	56.7	54.8	54.4	0.0014
Renal Impairment[c]	2.3	1.9	1.8	1.4	1.8	2.2	0.06
Cancer	5.13	3.37	3.37	2.83	3.5	3.3	0.004
Subjective Well-being							<0.0001
Poor	2.1	2	1.6	1.8	2.5	4.5	
Fair	24.7	24.6	24.7	25.8	29.8	34.8	
Good	62.2	63.3	64.7	63.1	59.7	54.9	
Excellent	11	10.1	8.9	9.2	8.1	5.8	

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Table 1. (*Continued*)

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Medications							
No. of Antihypertensives							<0.0001
0	0.5	1.9	6.2	14.6	19.2	19.8	
1	18.3	51.3	19.2	44.7	41.7	39.5	
≥2	51.3	46.8	44.6	40.7	39.1	40.8	
ACE Inhibitor	48.4	48.8	46.6	43.1	42.0	43.8	<0.0001
Calcium Antagonist	46.7	44.7	41.6	35.1	32.2	29.9	<0.0001
Diuretic	35.6	33.2	32.0	32.0	32.1	33.6	0.1
Lipid-Lowering Agent	45.9	43.3	38.2	37.7	35.1	31.9	<0.0001
Nitrates	37.3	34.5	33.7	34.6	36.9	38.2	<0.0001
Aspirin	56.6	55.2	54.1	57.4	57.7	57.6	0.0040
Antidiabetic Medication	23.5	25.0	24.3	21.5	22.0	21.5	0.0004

[a]Values expressed as percentage unless otherwise indicated. Percentages may not add to 100 due to rounding; [b]History of or currently taking antidiabetic or lipid-lowering medications; [c]History of or currently have elevated serum creatinine level, but less than 4 mg/dL (<354 μmol/L). Abbreviations: ACE, angiotensin-converting enzyme; BMI, body mass index; NYHA, New York Heart Association; SBP, systolic blood pressure; SD, standard deviation; TIA, transient ischemic attack.

age of 66.2±9.8 years), overweight, and racially diverse (with a high percentage of Hispanics), and evenly distributed between males and females. The average SBP was 150.9±19.5 mm Hg. Most patients (86.6%) were on 1 or more antihypertensive drug; 25.5% of the patients' SBP was <140 mm Hg at study entry, and 26.4% of the patients had SBP of >160 mm Hg. Almost half of the patients' SBPs were in the highest 2 categories: SBP >150 ≤ 160 and SBP >160 mm Hg. A total of 31.6% of all patients reported feeling fair/poor at study entry.

Self-Reported Subjective Well-being During Follow-Up

At 6 weeks, 20.7% of the patients reported feeling fair/poor, a significant improvement over the baseline ($P < 0.0001$). As the study follow-up progressed in time, the percentage of patients who reported fair/poor decreased further. At the 1 year visit, 17.9 % of patients reported feeling fair/poor, also a significant improvement over baseline (*P* for chi-squared test: <0.0001).

Systolic Blood Pressure During Follow-Up

The average SBP at each study visit is shown in Figure 1. Most of the SBP reduction occurred in the first 6 months of the treatment. After 6 weeks of study antihypertensive drug treatment, the average SBP reduced to 139.2±19.1 (mm Hg) and the percentage of patients in the 2 highest SBP categories had decreased to less than 25%. By 2 years of follow-up, only about 1 in 10 patients' SBP was in the

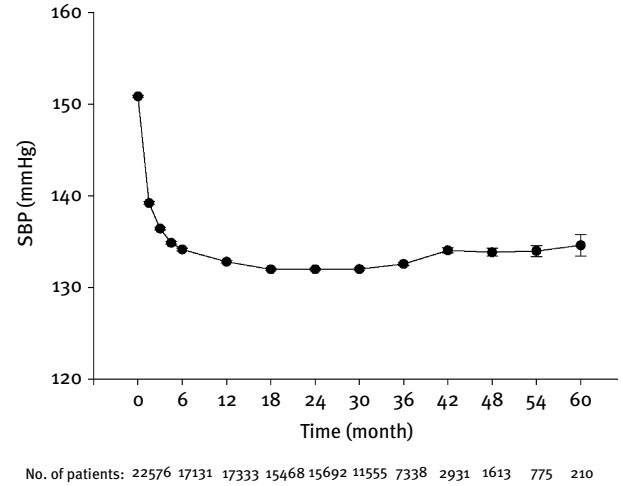

Figure 1. Mean SBP at each study protocol visit. Abbreviation: SBP, systolic blood pressure.

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2 highest SBP categories, 79.3% of the patients had SBP <140 mm Hg and the average SBP was 132.0±15.6 mm Hg. During follow-up, the percentage of patients in the lower SBP categories (categories 1–3) increased progressively and the percentage of patients in higher SBP categories (4–6) decreased.

Association of SBP and Risk for Feeling Fair/Poor SWB

SBP was highly associated with fair/poor SWB. The higher the SWB during follow-up, the higher the odds for reporting fair/poor SWB. The unadjusted OR and 95% CI versus SBP ≤120 mm Hg are shown in Table 2. None of the estimates of cross-time (month) correlation were significant.

The multivariable GEE estimation showed that the baseline SWB is the strongest predictor of SWB during the study. Patients who reported feeling fair/poor at baseline had 6 times higher odds of reporting fair/poor SWB during the study follow-up (OR: 6.67, 95% CI: 6.50–6.85, $P<0.0001$). After adjusting for baseline SWB of fair/poor, characteristics such as age (decades), gender, race/ethnicity, angina, diabetes, smoking, history of MI, stroke/TIA, and cancer, patients with higher SBP had higher odds of reporting SWB of fair/poor. Specifically, patients with SBP >150 – ≤160 had ~90% greater odds of feeling fair/poor than patients with SBP of ≤120 (OR: 1.90, 95% CI: 1.81–2.00, $P<0.0001$). Patients with SBP >160 had 2.5 times higher odds of reporting fair/poor SWB (OR: 2.53, 95% CI: 2.41–2.66, $P<0.0001$; Figure 2A).

Presence of angina was also strongly associated with increased odds of feeling fair/poor. Patients who experienced angina in the previous 4 weeks were 2.2 times more likely to feel fair/poor (OR: 2.2, 95% CI: 2.13–2.27, $P<0.0001$) compared to those who did not. Women had 24% higher odds of reporting feeling fair/poor than men (OR: 1.24, 95% CI: 1.20–1.27; Figure 2B). Other factors such as smoking history (OR: 1.29, 95% CI: 1.25–1.32), diabetes (OR: 1.26, 95% CI: 1.23–1.30), history of stroke/TIA (OR: 1.19, 95% CI: 1.14–1.25), MI (OR: 1.07, 95% CI: 1.04–1.10), older age (by decade, OR: 1.09, 95% CI: 1.08–1.11), and Black race (versus White, OR: 1.08, 95% CI: 1.04–1.13) were also associated with higher odds of fair/poor SWB. Hispanics and Asians are less likely to report feeling fair/poor than Whites (OR: 0.82, 95% CI: 0.79–0.84 and OR: 0.60, 95% CI: 0.50–0.73, respectively; Figure 2B).

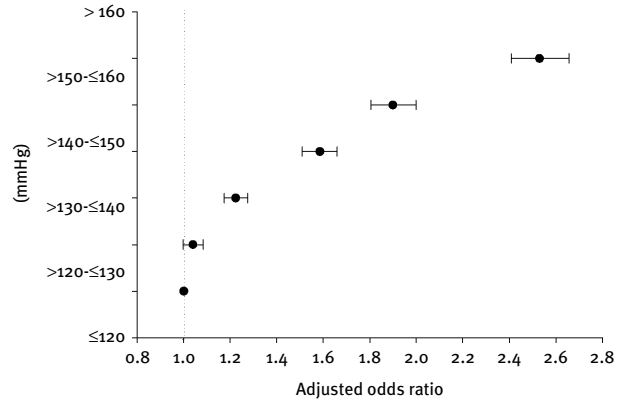

Figure 2A. Adjusted OR and CI of each SBP category for feeling fair/poor during the entire study (SBP ≤120 mm Hg was used as the reference group) after adjusting all the variables shown in Figure 2B. Abbreviations: CI, confidence interval; OR, odds ratio; SBP, systolic blood pressure.

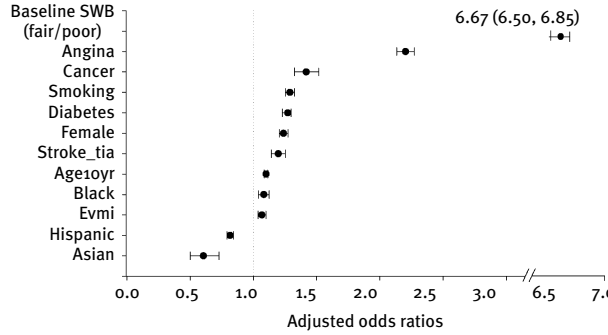

Figure 2B. Adjusted OR and 95% CI of other predictors for SWB of fair/poor in descending order (For race/ethnicity, "White" was used as the reference group; for all other variables, the absence of the condition was used as the reference group).
Abbreviations: CI, confidence interval; Evmi, history of myocardial infarction; OR, odds ratio; SWB, subjective well-being; TIA, transient ischemic attack.

Table 2. Unadjusted OR and 95% CI for Each SBP Category for the Odds of Reporting Fair/Poor SWB During Study

SBP (mm Hg)	OR (95% CI)	*p*
≤120	1 (1-1)	
>120 and ≤130	0.99 (0.96-1.03)	0.73
>130 and ≤140	1.14 (1.10-1.18)	<0.0001
>140 and ≤150	1.43 (1.37-1.49)	<0.0001
>150 and ≤160	1.76 (1.68-1.84)	<0.0001
>160	2.48 (2.37-2.59)	<0.0001

Abbreviations: CI, confidence interval; OR, odds ratio; SBP, systolic blood pressure; SWB,subjective well-being.

Discussion

Our results indicate that patients with a higher SBP at baseline or during treatment were more likely to experience suboptimal HRQOL during follow-up and this association was independent of other patient characteristics. More importantly, although generally considered an "asymptomatic"

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condition, our results show that high SBP is actually associated with a patient's general perception of quality of life. This association persisted even after controlling for angina and patient characteristics like smoking, diabetes, gender, prior stroke/TIA, history of MI, age, and race. This important finding provides evidence to suggest that hypertension is not completely "silent."

Others have proposed that symptoms of disease are the primary mediators of disease effects on HRQOL.[8] Thus, in patients with coronary disease, angina would be expected to be principal determinant of HRQOL.[9,10,11] Consistent with this notion, our findings show that experience of angina was also significantly associated with worse self-reported SWB.

Interestingly, women were consistently more likely to report fair/poor SWB than men during the study follow-up, which is in agreement with a previous report using the Seattle Angina Questionnaire to measure HRQOL in CAD patients[12] and another study in the Hispanic population.[13] These findings underline the fact that conclusions based on research performed on men with CAD may not be valid for women and unfortunately gender specific data are lacking. Clearly, more gender specific research data is needed.

Because of the race/ethnicity diversity of the INVEST population we were able to compare the HRQOL among Whites, Blacks, Hispanics, and Asians. Black patients had lower self-reported HRQOL than Whites in our elderly, hypertensive, stable CAD patients, which is consistent with some previous studies in different study populations.[14–16] The findings that Hispanics and Asian reported better HRQOL compared to Whites are a new and important addition to the HRQOL literature.

Our study is not without limitations. First, the findings reported are specific for clinically stable CAD patients with hypertension, age 50 years or older meeting the INVEST inclusion criteria. Although these inclusion criteria were very broad, the results should not be extrapolated to other populations. Second, we used a single-item questionnaire with 4 response options for SWB which collapses the more commonly used "Very Good" and "Good" categories into "Good," and may have reduced our ability to discriminate among those who were at the upper end of the scale. However, the single item SWB question is associated with other validated indicators of HRQOL (ie, SF-36), the 36-Item Short Form Health Survey. and poor clinical outcomes, specifically all-cause death and nonfatal stroke.[7] Use of a single-limited item SWB scale does not allow for a more complete assessment of all of the psychosocial or other aspects of a patient's life (work, finances, social relationships, education, living conditions, etc) that may play an important role in a patient's perception of overall well-being.

In conjunction with selected patient characteristics, high SBP, an important modifiable risk factor, is associated with impaired SWB among hypertensive CAD patients. These findings suggest that hypertension is not a "silent" condition in CAD patients and could have important implications for hypertension management.

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