

## Correlation Study on the Impact of Single-Pill Combination Antihypertensive Medication on Medication Adherence and Blood Pressure Control Among Community Hypertensive Patients: Postprint

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### Abstract

**Background** Single-pill combination (SPC) therapy for hypertension is an intensive treatment approach that can improve patient medication adherence and antihypertensive efficacy. Currently, there are few domestic studies reporting on medication adherence, blood pressure control status, and influencing factors of both among community-dwelling hypertensive patients taking SPC medications. **Objective** To investigate medication adherence, blood pressure control status, and influencing factors among community-dwelling hypertensive patients using SPC in Huai' an City, Jiangsu Province, and to explore the effects of self-efficacy and medication satisfaction on medication adherence and blood pressure control. **Methods** A cross-sectional study was conducted, randomly selecting 387 hypertensive patients taking SPC antihypertensive medications in Huai' an City, Jiangsu Province from June to December 2022. The Chinese version of the 8-item Morisky Medication Adherence Scale (MMAS-8), Hypertensive Patient Self-Efficacy Scale, and Treatment Satisfaction Questionnaire for Medication Second Edition (TSQM-) Chinese version were used to conduct questionnaire surveys among included patients. Patients were divided into a blood pressure control group (125 cases) and an uncontrolled blood pressure group (262 cases) based on blood pressure control status. Multivariate logistic regression was used to analyze factors influencing blood pressure control, and structural equation modeling was used to verify the effects of self-efficacy and medication satisfaction on medication adherence and blood pressure control. **Results** The blood pressure control rate among 387 hypertensive patients taking SPC medications was 32.30%. The proportions of unmarried/divorced/widowed and overweight/obese patients in the blood pressure control group were significantly lower than those in the uncontrolled

group, with statistically significant differences (both  $P < 0.05$ ). A total of 415 questionnaires were collected, with 387 valid questionnaires, yielding an effective response rate of 93.25%. Questionnaire results showed that scores for medication adherence, self-efficacy, and medication satisfaction in the blood pressure control group were significantly higher than those in the uncontrolled group ( $6.45 \pm 1.10$  vs  $6.00 \pm 1.50$ ,  $32.10 \pm 6.65$  vs  $30.65 \pm 6.66$ ,  $52.45 \pm 8.83$  vs  $48.27 \pm 11.85$ , all  $P < 0.001$ ). Overweight/obesity (OR=1.717, 95%CI=1.058~2.787,  $P=0.029$ ), medication adherence (OR=1.461, 95%CI=1.202~1.775,  $P < 0.001$ ), self-efficacy (OR=1.052, 95%CI=1.011~1.095,  $P=0.013$ ), and medication satisfaction (OR=1.025, 95%CI=1.000~1.051,  $P=0.048$ ) were influencing factors for blood pressure control in patients using SPC medications. Pearson correlation analysis showed positive correlations between medication adherence, self-efficacy, and medication satisfaction ( $r=0.294$ ,  $0.226$ ,  $0.280$ , respectively, all  $P < 0.05$ ). Structural equation modeling results indicated that both self-efficacy and medication satisfaction were positively correlated with medication adherence (path coefficients 0.29 and 0.13, respectively, both  $P < 0.05$ ), and medication adherence was positively correlated with blood pressure control status (path coefficient 0.15,  $P < 0.05$ ). Conclusion Blood pressure control status among community-dwelling hypertensive patients taking SPC medications in Huai' an City, Jiangsu Province is relatively poor. Patient overweight/obesity, medication adherence, self-efficacy, and medication satisfaction can all influence blood pressure control in patients using SPC medications. Improving self-efficacy and medication satisfaction among community-dwelling hypertensive patients taking SPC medications can effectively enhance patient medication adherence, thereby improving blood pressure control status.

## Full Text

### Abstract

**Background:** Single-pill combination (SPC) therapy for hypertension is an intensive treatment that can improve patient medication adherence and antihypertensive efficacy. However, few studies have examined the current status and influencing factors of medication adherence and blood pressure control among community-dwelling hypertensive patients taking SPC therapy in China. **Objective:** To investigate medication adherence, blood pressure control status, and their influencing factors among community hypertensive patients using SPC drugs in Huai' an, Jiangsu Province, and to explore the effects of self-efficacy and medication satisfaction on medication adherence and blood pressure control. **Methods:** This cross-sectional study randomly selected 387 hypertensive patients taking SPC antihypertensive drugs in Huai' an, Jiangsu Province from June to December 2022. Participants were surveyed using the Chinese version of the 8-item Morisky Medication Adherence Scale (MMAS-8), the Hypertension Patient Self-Efficacy Scale, and the Chinese version of the Treatment Satisfaction Questionnaire for Medication II (TSQM-II). Patients were divided into a blood pressure-controlled group

(n=125) and an uncontrolled group (n=262) based on their blood pressure control status. Multivariate logistic regression analysis was used to identify factors influencing blood pressure control, and structural equation modeling was employed to verify the effects of self-efficacy and medication satisfaction on medication adherence and blood pressure control. **Results:** The blood pressure control rate among the 387 hypertensive patients taking SPC drugs was 32.30%. The proportions of unmarried/divorced/widowed individuals and overweight/obese patients were significantly lower in the blood pressure-controlled group compared to the uncontrolled group (both  $P < 0.05$ ). A total of 415 questionnaires were collected, with 387 valid questionnaires yielding an effective response rate of 93.25%. Survey results showed that medication adherence, self-efficacy, and medication satisfaction scores were significantly higher in the blood pressure-controlled group than in the uncontrolled group ( $6.45 \pm 1.10$  vs.  $6.00 \pm 1.50$ ,  $32.10 \pm 6.65$  vs.  $30.65 \pm 6.66$ , and  $52.45 \pm 8.83$  vs.  $48.27 \pm 11.85$ , respectively; all  $P < 0.001$ ). Overweight/obesity (OR=1.717, 95%CI=1.058-2.787,  $P=0.029$ ), medication adherence (OR=1.461, 95%CI=1.202-1.775,  $P < 0.001$ ), self-efficacy (OR=1.052, 95%CI=1.011-1.095,  $P=0.013$ ), and medication satisfaction (OR=1.025, 95%CI=1.000-1.051,  $P=0.048$ ) were identified as influencing factors for blood pressure control in patients taking SPC drugs. Pearson correlation analysis revealed positive correlations between medication adherence, self-efficacy, and medication satisfaction ( $r=0.294$ ,  $0.226$ , and  $0.280$ , respectively; all  $P < 0.05$ ). Structural equation modeling demonstrated that both self-efficacy and medication satisfaction were positively associated with medication adherence (path coefficients=0.29 and 0.13, respectively; both  $P < 0.05$ ), and medication adherence was positively associated with blood pressure control (path coefficient=0.15,  $P < 0.05$ ). **Conclusion:** Blood pressure control among community hypertensive patients taking SPC drugs in Huai'an, Jiangsu Province is relatively poor. Overweight/obesity, medication adherence, self-efficacy, and medication satisfaction all influence blood pressure control in patients using SPC drugs. Improving self-efficacy and medication satisfaction among community hypertensive patients taking SPC drugs can effectively enhance medication adherence and thereby improve blood pressure control.

**Keywords:** Hypertension; Blood pressure control; Single-pill combination; Medication compliance; Structural equation modeling

## Introduction

Single-pill combination (SPC) therapy for hypertension, which contains two or more antihypertensive agents in a single tablet, represents a more effective intensive treatment approach. Compared with monotherapy or equivalent free combinations, SPC therapy improves medication adherence among hypertensive patients, though adherence remains below optimal levels [1]. Previous research has demonstrated that self-efficacy and medication satisfaction are important factors influencing patient medication adherence, and that enhancing self-efficacy and improving medication satisfaction can increase adherence and directly impact

disease outcomes [2-4]. While studies have individually examined the effects of self-efficacy and medication satisfaction on medication adherence, as well as the effect of adherence on blood pressure control, few have comprehensively investigated the mechanisms through which these factors influence both medication adherence and blood pressure control among hypertensive patients taking SPC drugs. This study therefore examines the correlations between self-efficacy, medication satisfaction, medication adherence, and blood pressure control in community hypertensive patients using SPC therapy, constructing a structural equation model to clarify the path relationships among these variables and provide a new perspective for improving medication adherence and blood pressure control in this population.

## Methods

### Study Design and Participants

This cross-sectional study employed a multi-stage random sampling method conducted from June to December 2022 in Huai'an, Jiangsu Province. Qingjiangpu District and Huaiyin District were selected as primary sampling units, from which 10 community health service centers were randomly chosen as study sites. Primary hypertensive patients with established diagnoses who were currently taking SPC antihypertensive drugs were recruited from these centers.

**Diagnostic Criteria:** (1) Blood pressure control targets followed the *2018 Revision of the Chinese Guidelines for the Prevention and Treatment of Hypertension* [5]. Body mass index (BMI) was calculated based on height and weight measurements. (2) Overweight/obesity criteria followed the diagnostic standards in the *Primary Care Guidelines for Obesity (2019 Edition)* [6]. (3) Orthostatic hypotension was defined according to the *Chinese Hypertension Health Management Standards (2019)* [7] as a decrease in systolic blood pressure  $\geq 20$  mmHg and/or diastolic blood pressure  $\geq 10$  mmHg within 3 minutes of transitioning from supine to standing position, with or without hypoperfusion symptoms.

**Inclusion Criteria:** (1) Met diagnostic criteria from the *2018 Revision of the Chinese Guidelines for the Prevention and Treatment of Hypertension* [5]; (2) Aged 18-80 years; (3) Maintained current antihypertensive treatment regimen for  $\geq 6$  months; (4) Had established resident health records and were enrolled in community-based hypertension chronic disease management.

**Exclusion Criteria:** (1) Patients with malignancies, decompensated cardiopulmonary function, or other severe complications; (2) History of psychiatric illness; (3) Pregnant or planning pregnancy; (4) Significant communication barriers or assessed as non-cooperative; (5) Not residing in the service area of selected community health centers; (6) Incomplete clinical data.

This study was approved by the Ethics Review Committee of the Affiliated Huai'an No.1 People's Hospital of Nanjing Medical University (approval num-

ber: KY-2023-049-01), and all participants provided informed consent prior to enrollment.

### Data Collection

All surveys were conducted by trained personnel. The purpose, significance, and instructions were explained to participants using standardized guidance, and questionnaires were distributed after obtaining consent. To avoid suggestion or guidance, investigators read questionnaire items and options aloud and recorded responses item by item based on participants' answers. Questionnaires were collected immediately upon completion.

Sample size was estimated at 5-10 times the maximum number of scale items, with a 20% attrition rate, yielding a required sample of 180-360 participants. To ensure data quality, 415 questionnaires were ultimately collected, with 387 valid questionnaires (effective response rate: 93.25%).

**General Information:** A customized questionnaire collected demographic and clinical data including name, sex, age, marital status, living alone status, highest-level diagnostic unit, hypertension duration, family history of hypertension, medication source, medical insurance type, and family doctor contract status. Physical examinations including height and weight measurements were completed on-site.

**Blood Pressure Measurement:** Before measurement, participants were asked about coffee or alcohol consumption and vigorous activity within 30 minutes to ensure stable condition. Participants rested for 5-10 minutes and emptied their bladders. Measurements were conducted by trained community health center staff using upper-arm electronic sphygmomanometers (HBP-1300, Omron Dalian Co., Ltd., cuff circumference 22-32 cm) that met Association for the Advancement of Medical Instrumentation (AAMI) standards. Supine brachial blood pressure was measured three times consecutively, then immediately upon standing at 0, 2, and 3 minutes. The arm was positioned at heart level during measurements, with 1-minute intervals between readings. The average of two readings was recorded; if systolic and/or diastolic differences exceeded 5 mmHg, a third measurement was taken and the average of three readings was used. Blood pressure control status was determined based on the *2018 Revision of the Chinese Guidelines for the Prevention and Treatment of Hypertension* [5], dividing participants into controlled and uncontrolled groups.

### Survey Instruments

**Chinese Version of the 8-item Morisky Medication Adherence Scale (MMAS-8)** [8]: Originally developed by Morisky in 1986 as a 4-item scale and revised to 8 items in 2008. Items 1-7 use dichotomous scoring (0/1), with item 5 reverse-scored. Item 8 uses a 5-point Likert scale ("never" to "all the time"), with "never" scored as 1 and "all the time" as 0. Total scores range 0-8, with higher scores indicating better adherence. Scores <6 indicate low adherence,

\$6 to <8 moderate adherence, and 8 high adherence [9]. The Chinese version has a Cronbach' s  $\alpha$  coefficient of 0.74.

**Hypertension Patient Self-Efficacy Scale:** Developed by Yang and Liu [10], this scale comprises 4 dimensions with 11 items using a 5-point Likert scale. Total scores range 0-44, with higher scores indicating greater self-efficacy. The scale has a Cronbach' s  $\alpha$  coefficient of 0.80 and test-retest reliability of 0.813.

**Chinese Version of the Treatment Satisfaction Questionnaire for Medication II (TSQM-II)** [2]: This scale includes 4 dimensions (effectiveness, side effects, convenience, and overall satisfaction) with 11 items. Item 3 assesses adverse drug reactions using "yes/no" scoring. The side effects dimension uses a 5-point Likert scale (1= "extremely dissatisfied" to 5= "not dissatisfied" ), while effectiveness, convenience, and overall satisfaction use a 7-point Likert scale (1= "extremely dissatisfied" to 7= "extremely satisfied" ). Higher scores indicate greater medication satisfaction. Cronbach' s  $\alpha$  coefficients for dimensions range 0.88-0.94, with overall test-retest reliability of 0.829.

### Data Entry and Quality Control

This study combined household surveys with telephone follow-up, all conducted with participants' permission to ensure authentic and reliable information. Investigators included community public health staff with primary care experience and postgraduate students in general practice who received specialized training. To control quality, two graduate students independently entered data, then compared databases. Inconsistent data were verified against original questionnaires and re-entered to ensure accuracy.

### Statistical Analysis

Data were analyzed using SPSS 22.0 and AMOS 26.0 software. Continuous variables with normal distribution were expressed as mean $\pm$ standard deviation ( $\bar{x}\pm s$ ) and compared between groups using t-tests. Categorical data were expressed as percentages and compared using  $\chi^2$  tests. Statistically significant factors from univariate analysis were included as independent variables in multivariate logistic regression analysis to explore influencing factors of blood pressure control in patients taking SPC drugs. Pearson correlation analysis examined relationships among medication adherence, self-efficacy, and medication satisfaction dimensions. AMOS 26.0 was used to analyze path relationships and construct structural equation models.

Model fit indices and goodness-of-fit criteria included: (1) chi-square/degrees of freedom ratio ( $\chi^2/df$ ) <8.0; (2) root mean square error of approximation (RMSEA) <0.08; (3) standardized root mean square residual (SRMR) <0.05; (4) goodness-of-fit index (GFI) >0.9; (5) comparative fit index (CFI) >0.9; (6) adjusted goodness-of-fit index (AGFI) >0.9; (7) normed fit index (NFI) >0.9; and (8) incremental fit index (IFI) >0.9. When all conditions were met, the

structural equation model demonstrated adequate overall fit, indicating good support from observed data. All statistical tests were two-tailed, with  $P < 0.05$  considered statistically significant.

## Results

### Comparison of Clinical Characteristics Between Blood Pressure-Controlled and Uncontrolled Groups

This study included 387 community hypertensive patients taking SPC drugs, comprising 125 in the blood pressure-controlled group and 262 in the uncontrolled group, yielding a blood pressure control rate of 32.30%. The proportions of overweight/obese individuals and unmarried/divorced/widowed patients were significantly lower in the controlled group compared to the uncontrolled group ( $P < 0.05$ ). No statistically significant differences were observed between groups in sex, age, medical insurance type, diagnostic unit level, living alone status, disease duration, family doctor contract status, family history, orthostatic hypotension, medication source, comorbidities, or concomitant medications ( $P > 0.05$ ).

### Usage Patterns of Different SPC Types Among Community Hypertensive Patients

Among community hypertensive patients, traditional SPC usage rate was 54.78% (212/387), while modern SPC usage rate was 45.22% (175/387). The three most commonly used drugs were Compound Reserpine [127 cases (32.82%)], Irbesartan Hydrochlorothiazide [115 cases (29.72%)], and Zhenju Antihypertensive Tablets [51 cases (13.18%)]. Additional details are presented in .

### Scale Scores Among Community Hypertensive Patients Taking SPC Drugs

The mean MMAS-8 score was  $6.14 \pm 1.40$ , the mean Hypertension Patient Self-Efficacy Scale score was  $31.12 \pm 6.69$ , and the mean TSQM-II score was  $49.62 \pm 11.13$ . Dimension-specific scores are shown in through . Medication adherence, self-efficacy, and medication satisfaction scores were significantly higher in the blood pressure-controlled group compared to the uncontrolled group ( $P < 0.001$ ).

### Multivariate Logistic Regression Analysis of Blood Pressure Control Influencing Factors

Using blood pressure control status as the dependent variable (1=controlled, 0=uncontrolled), multivariate logistic regression analysis included statistically significant factors from univariate analysis as independent variables: overweight/obesity (coded: 1=no, 0=yes), marital status (coded: 1=married, 0=unmarried/divorced/widowed), medication adherence (actual MMAS-8

score), self-efficacy (actual self-efficacy scale score), and medication satisfaction (actual TSQM-II score). Results showed that overweight/obesity (OR=1.717, 95%CI=1.058-2.787, P=0.029), medication adherence (OR=1.461, 95%CI=1.202-1.775, P<0.001), self-efficacy (OR=1.052, 95%CI=1.011-1.095, P=0.013), and medication satisfaction (OR=1.025, 95%CI=1.000-1.051, P=0.048) were influencing factors for blood pressure control in patients taking SPC drugs .

### **Pearson Correlation Analysis of Medication Adherence with Self-Efficacy and Medication Satisfaction**

Correlation analysis revealed positive correlations between self-efficacy and medication adherence (r=0.294, P<0.001), medication satisfaction and medication adherence (r=0.226, P<0.001), and self-efficacy and medication satisfaction (r=0.280, P<0.001) among community hypertensive patients taking SPC drugs. Medication adherence was positively correlated with all four dimensions of self-efficacy and all four dimensions of medication satisfaction (P<0.05) .

### **Structural Equation Model of Medication Adherence, Self-Efficacy, Medication Satisfaction, and Blood Pressure Control**

Based on literature [2-4] and the above results, this study constructed a structural equation model examining relationships among medication adherence, self-efficacy, medication satisfaction, and blood pressure control in community hypertensive patients taking SPC drugs [Figure 1: see original paper]. Fit indices indicated good model fit ( $\chi^2=71.094$ , df=42,  $\chi^2/df=1.693<8.0$ , RMSEA=0.042<0.08, AGFI=0.950, NFI=0.932, IFI=0.971, CFI=0.970). Results showed that both self-efficacy and medication satisfaction positively influenced medication adherence, and medication adherence positively influenced blood pressure control (P<0.05). Path coefficients and significance levels are presented in .

## **Discussion**

SPC antihypertensive drugs have demonstrated good efficacy, safety, and accessibility, becoming one of the main treatments for hypertension [1,11]. This study examined factors influencing medication adherence and blood pressure control among community hypertensive patients taking SPC drugs, yielding important insights for improving clinical management.

The study included 387 community hypertensive patients taking SPC drugs, with traditional SPC usage higher than modern SPC usage. The sample comprised 57.11% females, 92.25% aged  $\geq 65$  years, and 59.69% with disease duration  $\geq 10$  years, consistent with hypertension epidemiology showing higher prevalence in older adults and higher rates in women after middle age [12]. Most participants (63.57%) had employee medical insurance, 65.63% were diagnosed at municipal-level hospitals or above, and 89.66% had contracted family

doctors, indicating relatively good access to healthcare resources. Hospital prescriptions accounted for 64.48% of medication sources. National hypertension survey data from 2012-2015 showed that 37.5% of treated hypertensive patients in China achieved blood pressure control [13]. In contrast, this study found a control rate of only 32.30% among patients taking SPC drugs, lower than the national average.

Multiple physiological and socioeconomic factors influence blood pressure control in patients taking SPC drugs. This study found that overweight/obese patients had poorer blood pressure control with SPC therapy, while those with high medication adherence, high self-efficacy, and high medication satisfaction achieved better control. Overweight/obese individuals may have lower health consciousness, making blood pressure control more challenging even with SPC therapy. Hypertension requires long-term, often lifelong, treatment, and medication represents the most important preventive and control measure. Good medication adherence plays a crucial role in blood pressure control. The European Society of Cardiology hypertension management guidelines identify poor adherence as a primary cause of inadequate blood pressure control [14], consistent with our findings.

Medication adherence is influenced by multiple factors including residence location, related policies, life stress, medication costs, self-rated health, sleep disorders, and alcohol consumption [15]. MMAS-8 scores indicated moderate adherence levels among SPC users in Huai' an. The structural equation model demonstrated positive effects of both self-efficacy and medication satisfaction on medication adherence, which in turn positively affected blood pressure control. Self-efficacy and medication satisfaction were positively correlated with medication adherence, consistent with previous research [2-3]. Self-efficacy refers to an individual' s perception and belief in their ability to control their actions. Individuals with high self-efficacy tend to believe in their problem-solving capabilities and adopt positive coping strategies when facing challenges [16]. Patients with high self-efficacy demonstrate better self-management [17] and receive more social support, which reinforces their confidence in maintaining medication adherence. They possess stronger self-management abilities, enabling them to overcome psychological and behavioral barriers, maintain confidence, and sustain healthy behaviors, thereby achieving optimal blood pressure control. This suggests that healthcare providers can enhance patient confidence and improve adherence through motivational interviewing and vicarious learning experiences based on self-efficacy theory.

Medication adherence is also influenced by medication satisfaction, with evidence showing that higher satisfaction correlates with better adherence [4]. This necessitates effective communication between physicians and patients to improve understanding of hypertension and its treatment. Strategies may include patient education and counseling, family member involvement, active patient engagement in decision-making, and training healthcare providers in patient consultation and management.

Poor medication adherence threatens the potential cardiovascular benefits of antihypertensive therapy, potentially leading to increased stroke, myocardial infarction, and cardiovascular mortality. In developing countries, antihypertensive treatment is among the most cost-effective measures for reducing cardiovascular mortality and morbidity [18]. This study identified patient self-efficacy and medication satisfaction as influencing factors for medication adherence, suggesting that future interventions targeting these domains could improve adherence and blood pressure control among patients taking SPC drugs.

Blood pressure control among community hypertensive patients taking SPC drugs in Huai'an, Jiangsu Province is relatively poor. Overweight/obesity, medication adherence, self-efficacy, and medication satisfaction all influence blood pressure control in this population. Improving self-efficacy and medication satisfaction can effectively enhance medication adherence and thereby improve blood pressure control.

**Limitations:** First, this cross-sectional study has inherent limitations in establishing causal relationships. Second, the study population consisted primarily of elderly patients aged  $\geq 65$  years, who may have cognitive impairment affecting self-report accuracy or may conceal information considered private. Finally, the study included only hypertensive patients taking SPC drugs, limiting generalizability to all hypertensive patients. Further research is needed to address these limitations.

**Author Contributions:** Chen Danxiang conceptualized the study, designed the research, implemented the investigation, and wrote the manuscript. Chen Danxiang and Xie Shu collected and organized data, performed statistical analysis, and created tables and figures. Wang Li and Zhang Hao revised the manuscript. Li Xueqin was responsible for quality control, overall review, and supervision.

**Conflict of Interest:** The authors declare no conflicts of interest.

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