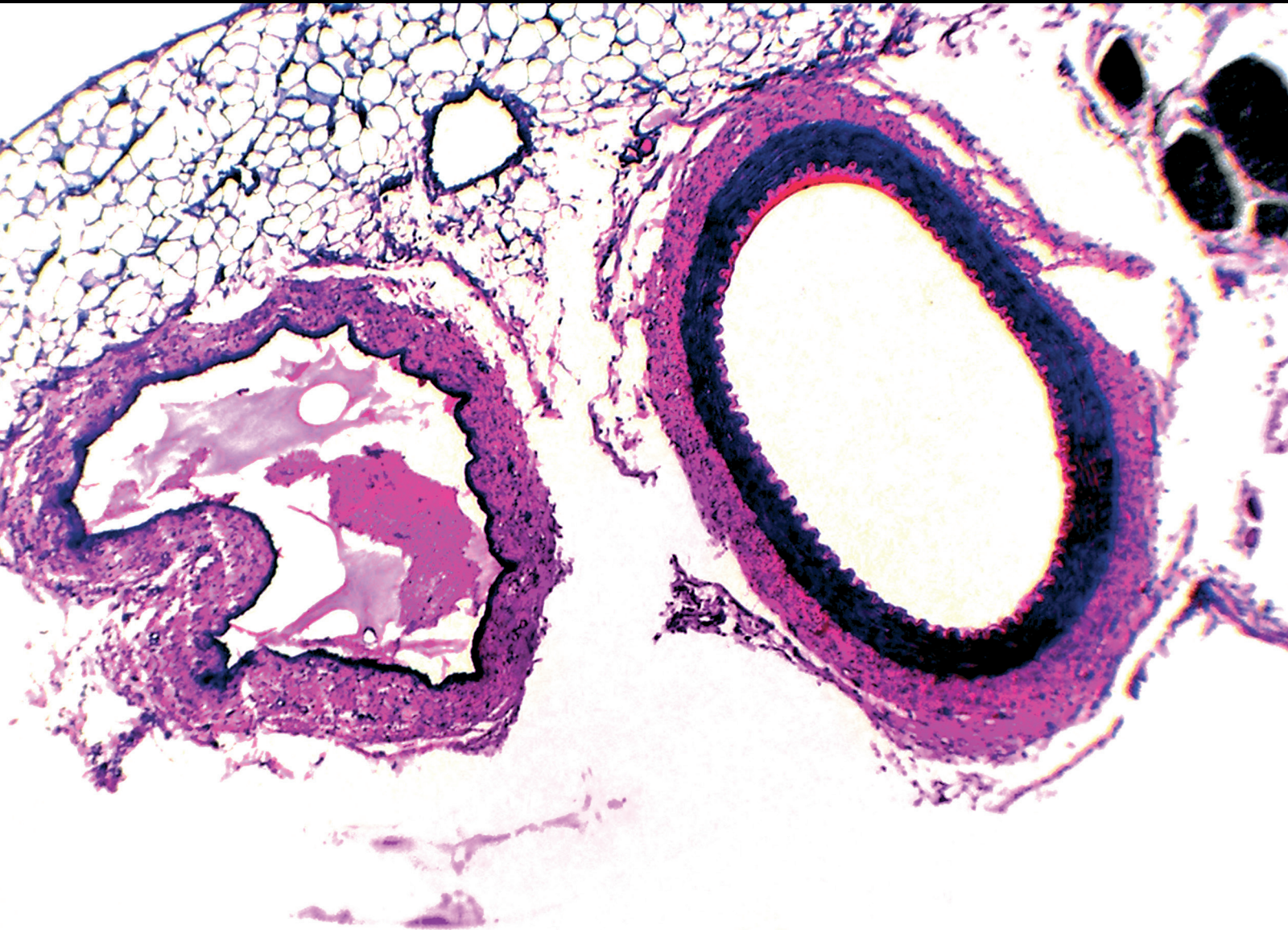


Nonpharmacologic Interventions in Prevention and Treatment of Hypertension

Lead Guest Editor: Omotayo O. Erejuwa

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International Journal of Hypertension

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Editorial

Nonpharmacologic Interventions in Prevention and Treatment of Hypertension

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Hypertension contributes to high rates of mortality and morbidity in both developing and developed countries. It predisposes individuals to several chronic diseases including stroke and other cardiovascular diseases. Predisposing factors such as sedentary lifestyles, unhealthy dietary habits, and physical inactivity are associated with its growing prevalence over the years. Besides social-economic factors, increased incidence of diabetes and obesity as well as modernized lifestyles plays important roles in the growing prevalence of uncontrolled hypertension, in particular in developing countries.

Currently, despite availability of several antihypertensive drugs, attaining an adequate blood pressure control is still a challenge. This can be attributed to several factors. For example, many of the existing antihypertensive agents do not modulate oxidative stress, which is an important pathophysiological pathway for the development of hypertension and several of its complications. Poor medication adherence, reduced drug effectiveness, drug unaffordability or unavailability, and side/adverse effects of medications are additional important obstacles that weigh significantly in our ability to control the disease. To address some of these limitations,

attention has been paid in recent years to the use of various nonpharmacologic interventions as a more viable alternative to treat the disease.

This special issue reports on the current status of non-pharmacologic approaches taken thus far across the world, in the prevention and treatment of hypertension. Several contributions were received from researchers in most of the continents. After stringent and thorough reviewing process, nine manuscripts (six original research, one clinical study, and two review articles) were accepted for publication.

H. H. Alhawari et al. assessed the frequency of hypertension among healthy university students and its association with gender, body mass index (BMI), smoking, and family history of both hypertension and cardiovascular diseases. They found significant gender differences in both systolic and diastolic blood pressure (i.e., higher in males as compared to females). Upon comparison of the mean difference in both systolic and diastolic blood pressure with BMI, there were significant differences in both systolic and diastolic blood pressure. First-degree family history of both hypertension and cardiovascular diseases was also found to affect systolic but not diastolic blood pressure. G. Musinguzi et al.

investigated and identified factors influencing compliance and health seeking behavior among hypertensive patients, being related to health systems and patient socioeconomic and structural environment. These include self-medication and self-prescription of antihypertensive drugs as well as marketing of herbal remedies. H. Javadzade et al. assessed the effectiveness of a theory-based self-care intervention with the application of health literacy approaches in hypertensive patients and limited health literacy. The results have a potential to assist with the development of a theoretical framework for self-care intervention in patients with high blood pressure and limited health literacy. T. M. Dokunmu et al. assessed the risk of developing hypertension in healthy adult Nigerian population. Prehypertension was found in 36.8% population and elevated blood pressure in 31% individuals with hypertensive symptoms. The researchers found that age more than 35 years was an independent risk and this increases to 26.48 in the presence of prediabetes and random blood glucose greater than 100 mg/dL. Large scale screening and management of hypertension are recommended to reduce the burden of the disease. A. Larki et al. determined the factors that influence adherence to self-care behaviors among low health literacy hypertensive patients based on health belief model. The researchers found that designing and implementing educational programme to increase self-efficacy of patients and promote their beliefs about perceived susceptibility and severity of complications may improve self-care behaviors among low health literacy hypertensive patients.

E. Drevenhorn proposed a middle-range theory of nursing in hypertension care. Patients related concepts such as attitude and beliefs concerning health were presented. The researcher highlighted the clinical and research implications of the theory. Hypertension is a chronic disease that necessitates long-term self-management. Using a semistructured interview guide, K. D. Wright et al. described the process in which African American older adults and nurse researchers cocreated an intervention to address stress in the self-management of hypertension. Based on participants feedback, four biweekly (2-hour) group sessions which incorporated patients suggestions and concerns were created. Though it may be of significant benefits, further studies are required to test the generalizability of this technique. M. Horiuchi et al. investigated the effects of resistance exercise under hypoxia on postexercise in eight healthy young males. The findings suggested that hypoxic condition elicits greater impact on hypotension following resistance exercise (in comparison to normoxia). The data also suggest that the underlying mechanisms for the attenuation of hypotension after resistance exercise may vary between normoxia and hypoxia. Romani presented a review paper that underscores the beneficial effects of magnesium on blood pressure maintenance.

The issue highlights the importance of treatment and control of blood pressure via nonpharmacologic approaches. It thus reinforces the need for researchers to intensify more research in this aspect of hypertension management. This may help to reduce drastically the increasing prevalence and burden of hypertension worldwide.

Conflicts of Interest

The editors declare that they have no conflicts of interest regarding the publication of this special issue.

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We would like to thank all the authors who submitted their works to the special issue as well as the reviewers who have spared their valuable time in reviewing the submitted manuscripts.

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Clinical Study

Impact of Resistance Exercise under Hypoxia on Postexercise Hemodynamics in Healthy Young Males

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We investigated the effects of resistance exercise under hypoxia on postexercise hemodynamics in eight healthy young males. The subjects belonged to a track & field club (sprinters, hurdlers, and long jumpers) and engage in regular physical training (1-2 h per day, 3-5 days per week). Each participant performed eight sets of bilateral leg squats with a one-minute interval under normoxia (room air) and hypoxia (13 % FiO₂). During a 60-minute recovery, we set normoxic condition either after normoxic or hypoxic exercise. These two experimental protocols (normoxia and hypoxia) were performed in a random order with a one-week washout period. The leg squat exercise consists of 50 % 1-RM (14 repetitions) × 5 sets and 50% 1-RM (repetitions max; 7 repetitions) × 3 sets. The resting period between each set was 1 min, and a total of 91 repetitions were performed. Blood pressure, heart rate (HR), and several biomarkers were measured pre- and postexercise. The mean arterial pressure (MAP) significantly decreased after exercise compared to the pre-exercise values under both conditions ($P < 0.05$). The MAP at 20 and 30 min of recovery in hypoxia was significantly lower than in normoxia ($P < 0.05$, respectively). The antidiuretic hormone significantly increased after 60 min of recovery in both conditions; moreover, the values in hypoxia were significantly higher than those in normoxia ($P < 0.05$). The delta changes in MAP from baseline (pre-exercise) were significantly related to changes in HR from baseline in normoxia ($r = 0.560$, $P < 0.001$) but not in hypoxia. These results suggest that the hypoxic condition elicits greater hypotension after resistance exercise in comparison to normoxia. Moreover, the underlying mechanisms for the attenuation of hypotension after resistance exercise may differ between normoxia and hypoxia.

1. Introduction

In healthy individuals, an acute single bout of physical exercise elicits reductions in arterial blood pressure for approximately 2 h when compared to the baseline (pre-exercise) levels; this phenomenon is so-called postexercise hypotension (PEH) [1–3]. In addition, recent findings suggest that the magnitude of reductions in blood pressure (BP) with acute exercise may be associated with chronic reductions in the resting BP caused by exercise training [4, 5]. These results suggest that PEH with acute exercise may be relevant for predicting the long-term effects of BP changes.

Although these studies were conducted with aerobic exercise [4, 5], several studies have observed the occurrence of PEH after acute resistance exercise [6–10]. Moreover, a recent meta-analysis revealed that a single bout of resistance exercise can lower the BP in normotensive and hypertensive populations and the use of larger muscle groups resulted in greater BP reductions after resistance exercise [11]. Resistance exercise may exert some additional advantages; for example, resistance exercise is recommended for prevention of sarcopenia, wherein age-induced muscular degeneration often leads to compromised performance in activities of daily living [12]. Moreover, it has been suggested that resistance exercise

in hypoxia reportedly has beneficial effects in terms of increased muscle strength and size [13, 14]. However, it should be noted that greater PEH may frequently cause syncope after exercise [15] and higher intensity exercise induces a postexercise syncope compared to lower intensity exercise [16]. These results suggest that negative effects of PEH should also be considered, in particular, higher exercise intensity (e.g., high intensity aerobic or resistance exercise). Indeed, it was reported that the arterial blood pressure reached 320/250 mmHg during the maximal bilateral leg press [17] but the pressure subsequently fell rapidly after lifting [18]. As a result, the cerebral perfusion pressure falls below the pre-exercise levels, leading to an increased risk of syncope [18, 19]. Indeed, we reported that, after prolonged leg cycling, there was a greater reduction in the mean arterial blood pressure (MAP), and the decrease in MAP was positively related to decreases in cerebral oxygenation only in hypoxia [20]. These results suggest that resistance exercise in hypoxia may involve an increased risk of syncope even for healthy individuals, indicating that clarification of the mechanisms of PEH after resistance exercise in hypoxia is important. However, little is known about how resistance exercise in hypoxia may affect postexercise hemodynamics.

The aim of this study, therefore, was to investigate the influence of resistance exercise in hypoxia on postexercise hemodynamics in healthy young males. We hypothesized that resistance exercise in hypoxia elicits greater reductions in arterial blood pressure than in normoxia. To test this hypothesis, we used bilateral leg squats at 50% 1-RM (repetition max) with the inspiration of oxygen (FiO_2) at ~13% based on a previous study [21]. In addition, we measured several potent vasoconstrictors (antidiuretic hormone and aldosterone) and vasodilators (human atrial natriuretic peptide and adenosine) that may influence BP regulation.

2. Methods

2.1. Participants. This study was approved by the Ethical Committee of the University of Yamanashi in Japan and was performed in accordance with the guidelines of the Declaration of Helsinki (No: 201606). Eight healthy male subjects with a mean age of 19.9 ± 0.8 years, a height of 170.0 ± 3.1 cm, and a body mass of 65.1 ± 11.3 kg (mean \pm standard deviation [SD]) participated in this study. The subjects belonged to the track & field club at the University of Yamanashi (sprinters, hurdlers, and long jumpers) and engage in regular physical activity (1-2 h per day, 3-5 days per week). None of the subjects had been exposed to an altitude higher than 1500 m within the six months prior to the study. All subjects were nonsmokers and had no prior history of cardiovascular disease (i.e., hypertension, diabetes, or hyperlipidemia) or orthopedic disease. After receiving a detailed explanation of the study, including the procedures, possible risks, and benefits of participation, each subject signed an informed consent form.

2.2. Control of Diet and Physical Activity. Throughout the study, including the washout period (*please refer to the experimental procedures*), the subjects were asked to avoid alcohol

consumption and were only allowed to drink water. The diets consumed by the subjects on the night before the day of the study and the breakfast on the day of the study (when resistance exercise was performed in normoxia or hypoxia) were controlled. Briefly, the same dinner (containing: energy 967 kcal, protein 27 g, fat 30.5 g, carbohydrate 146 g, and sodium 1457 mg) and breakfast (energy 320 kcal, protein 3 g, fat 0 g, carbohydrate 80 g, and sodium 112 mg) were prepared for all the subjects. Strenuous exercise was prohibited 48 h before each main study session.

2.3. Experimental Procedures. The subjects were requested to abstain from caffeinated beverages for 12 h before each session and from strenuous exercise and alcohol for 24 h before each session. Throughout all the study sessions, we carefully controlled the room temperature at $20 \pm 1^\circ\text{C}$ to prevent the effects of change in BP, and external stimuli were minimized. All subjects performed two trials: (a) normobaric normoxic exercise (room air; equivalent altitude to 400 m) and (b) normobaric hypoxic exercise (fraction of inspired oxygen: $\text{FiO}_2 = 0.13$). These two trials were performed in a random order and at the same time (8:30–11:30) of the day to avoid the effect of the circadian rhythm, with at least a 1-week washout period. During this washout period, the subjects were asked to maintain their usual life and to avoid strenuous exercise. In the hypoxic trial, a 5-minute normoxic sitting rest condition was set while breathing room air. After this period, a 10-minute sitting and a 5-minute standing rest, followed by the bilateral leg squat exercise, was set while breathing hypoxic gas ($\text{FiO}_2 = 0.13$). Thereafter, a 60-minute sitting recovery was set while breathing room air (Figure 1). Hypoxic gas was supplied via a 200 liter Douglas bag reservoir through a two-way, nonbreathing valve and face mask using a hypoxic generator system (Hypoxico Everest Summit II: Will Co., Ltd., Tokyo, Japan), as previously reported in our recent study [22]. The inspired oxygen concentration was verified before and after each experiment (AE-310; Minato Medical Science, Osaka, Japan). In the normoxic trial, the same protocol as the hypoxic trial was adopted, but the subjects breathed room air throughout the study. The resistance exercise consisted of bilateral leg squats (1 repetition/2 sec) at 50% of 1-RM for eight sets with 1-minute intervals based on a previous study [21] and preliminary test in our laboratory. During the first five sets, they performed 14 reps, while during the last three sets, they performed seven reps. Thus, there was a total of 91 reps for the leg squats ($14 \text{ reps} \times 5 \text{ sets} + 7 \text{ reps} \times 3 \text{ sets}$). The 1-RM trials were designed using increments of 10 kg until 60–80% of the perceived maximum was reached. The load was then gradually increased by small weights (2.5–5 kg) until lift fail, which was defined as the participant's failure to maintain proper form or to completely lift the weight. Proper technique and a complete range of motion were required for each successful 1-RM trial [23]. For further confirmation, each subject repeated the 1-RM trials, and we confirmed the same 1-RM for all the subjects. No injuries were observed during the 1-RM testing. This test was performed 1 week before the main study. The last acceptable lift with the highest possible load was determined as 1-RM.

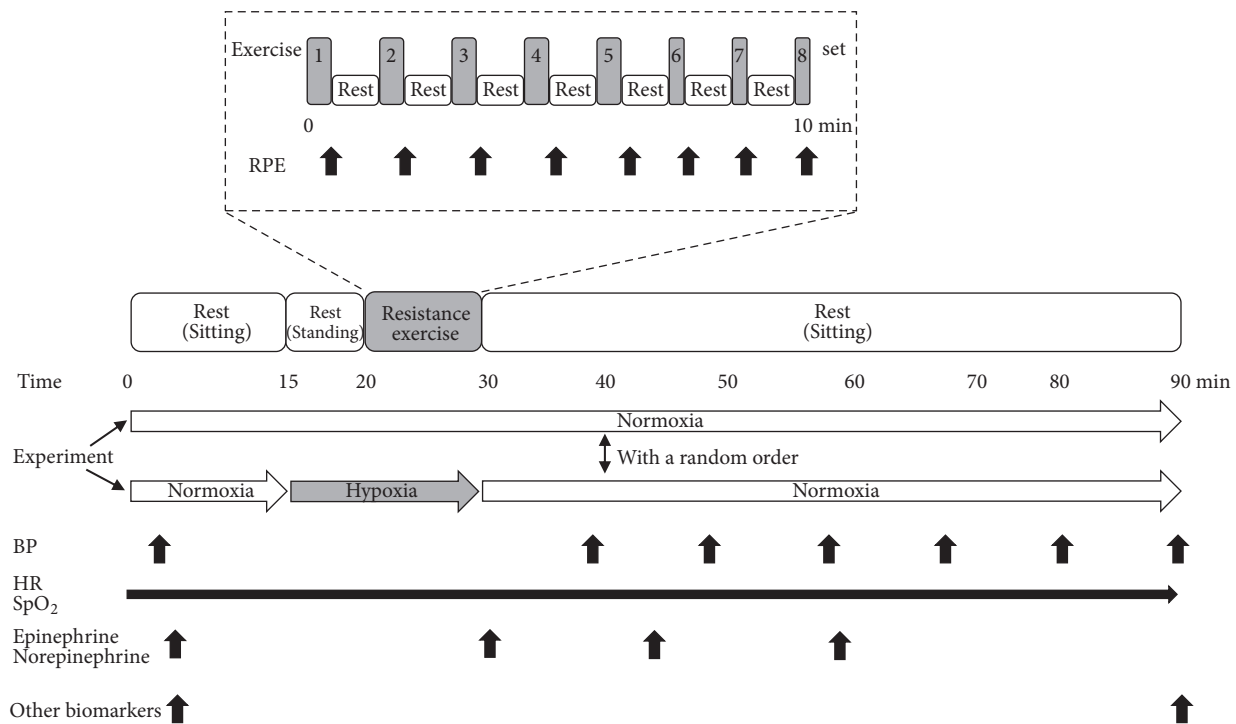


FIGURE 1: Experimental protocol of the present study. BP: blood pressure, HR: heart rate, and SpO₂: arterial oxygen saturation. RPE: rate of perceived exertion. Black arrows indicate measuring points and periods.

2.4. Measurements. BP was measured by the oscillometric method (HEM-907, OMRON, Tokyo, Japan) at baseline (pre-exercise) and at 10, 20, 30, 40, 50, and 60 min after exercise. At rest, BP was measured twice, and the average BP of the two measurements was considered as the subject's BP value. We also confirmed that the difference in the SBP or DBP was < 5mmHg compared to the values of one before measurement at rest [24]. According to the technical details provided by the manufacture (Omron, Co., Ltd., Tokyo, Japan), this device can adjust for different arm circumference (e.g., using different width of cuffs). Indeed, the validity of this device (e.g., the values of repeated measurements were different by < 5 mmHg) has been confirmed in previous studies [25–27]. During 60 min recovery period, BP was measured once to minimize the time course effect. Heart rate (HR) and arterial oxygen saturation (SpO₂) were continuously monitored using a wireless HR monitor (RS 800CX, Polar Electro, Japan) and automatic vital sensor (TM-256, A&D, Tokyo, Japan), respectively, throughout the experiment.

2.5. Blood Sampling and Analysis. Venous blood samples (20 ml) were taken from the antecubital vein at baseline and after 60 min of recovery. Samples were immediately centrifuged at 3000 rpm for 15 min at 4°C (MX-300 Tomy Seiko Co, Ltd., Tokyo, Japan) to separate the plasma and serum and were then frozen at -80°C for further analysis of the antidiuretic hormone (ADH), aldosterone, human atrial natriuretic peptide (hANP), adenosine, osmotic pressure (OSM), and free fatty acid (FFA) by SRL Co. Ltd. (Tokyo, Japan).

2.6. Data Analysis. The mean arterial pressure (MAP) was calculated using the following:

$$\text{MAP} = \frac{[\text{systolic BP (SBP)} - \text{diastolic BP (DBP)}]}{3} + \text{DBP} \quad (1)$$

The values of HR and SpO₂ were adopted at baseline, immediately after each set of leg squats and after 1, 2, 5, 10, 20, 30, 40, 50, and 60 min of recovery for further analysis. These values were averaged during the last 1 min at sitting baseline and during the 10 s immediately after each exercise and each recovery period.

2.7. Statistics. The values are expressed as the mean ± SD. Two-way repeated-measures with pairwise (Dunnett) post hoc tests were used to evaluate the changes in all physiological variables across different oxygen levels. First, as these variables were continuous variables, we analyzed them as parametric dataset. However, the sample size was small; therefore, equal variance failed in the variables, and Friedman nonparametric and pairwise (Scheffe) post hoc tests were used. The Spearman correlation coefficient was used for the relationship between changes in the MAP and HR from baseline to the values during recovery periods. A *P* value of less than 0.05 was considered statistically significant. Statistical analyses were performed using commercial software packages (Sigma Stat 3.5; Huliniks, Chicago, IL, USA).

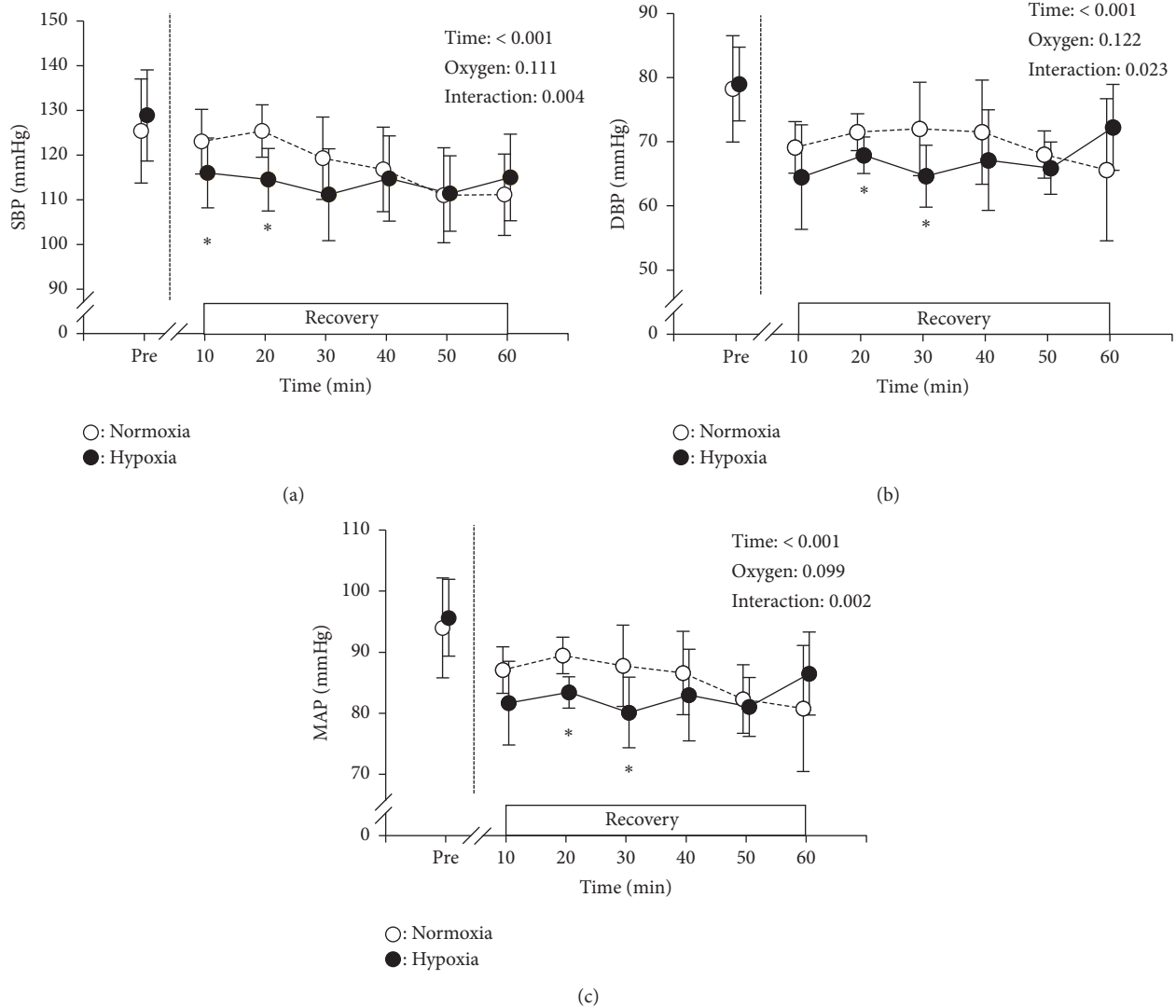


FIGURE 2: Changes in systolic blood pressure (SBP: panel (a)), diastolic blood pressure (DBP: panel (b)), and mean arterial blood pressure (MAP: panel (c)) at baseline (pre) and during 60 min recovery under normoxia (open circles) and hypoxia (closed circles). * indicates a significant difference between normoxia and hypoxia within the same time period.

3. Results

The changes in BP variables are shown in Figure 2. There were no significant differences in the pre-exercise values of SBP, DBP, and MAP between normoxia and hypoxia. Significant main effect for time and interaction (time \times oxygen) was observed for all BP variables. The SBP after 10 and 20 min of recovery in hypoxia was significantly lower than in normoxia ($P < 0.05$). Similarly, the DBP and MAP after 20 and 30 min of recovery in hypoxia were also lower than in normoxia ($P < 0.05$). Moreover, the SBP after 30 min and the MAP after 10 min of recovery in hypoxia showed lower values than in normoxia ($P < 0.1$).

The HR during the first five sets of exercise increased from about 150 bpm to 175 bpm, while they decreased slightly during the last three sets to \sim 160 bpm. After eight sets of exercise, the HR decreased acutely within the first 2 min and then decreased gradually until 60 min after exercise.

There were no significant differences in HR at any of the time points between normoxia and hypoxia (Figure 3(a)). SpO₂ decreased \sim 10% during exercise in the normoxic trial and \sim 20% in the hypoxic trial. During recovery, the SpO₂ in both trials recovered to baseline values within 1 min. There were significant differences in SpO₂ between trials for each exercise set, but no differences were observed at baseline or during recovery (Figure 3(b)).

Table 1 shows the biomarker changes between normoxia and hypoxia. A significant main effect for time (pre vs. post) was observed in ADH, aldosterone, hANP, and OSM ($P < 0.05$). Additionally, a significant main effect for the condition (normoxia vs. hypoxia) was observed in ADH, resulting in the values for ADH after exercise in hypoxia being significantly higher than in normoxia.

The baseline values (pre-exercise) for both epinephrine and norepinephrine showed similar values between conditions. Immediately after exercise, both values remarkably

TABLE 1: Blood biomarkers between pre- and poststudy in two different oxygen conditions.

		Normoxia	Hypoxia	Time	Oxygen	Interaction
ADH, pg ml ⁻¹	Pre	1.48 ± 1.56	1.59 ± 1.16	0.015	0.023	0.220
	Post	2.35 ± 1.39 [†]	3.44 ± 2.27 ^{*†}			
Aldosterone, pg ml ⁻¹	Pre	153 ± 38	161 ± 26	<0.001	0.401	0.336
	Post	267 ± 83 [†]	313 ± 87 [†]			
hANP, pg ml ⁻¹	Pre	16.5 ± 7.6	16.1 ± 7.4	0.024	0.966	0.456
	Post	11.8 ± 3.1 [†]	12.5 ± 4.6 [†]			
Adenosine, u l ⁻¹	Pre	20.6 ± 8.7	19.3 ± 7.0	0.844	0.350	0.429
	Post	20.9 ± 8.2	19.2 ± 6.1			
OSM, mOsm kgH ₂ O ⁻¹	Pre	283 ± 1	285 ± 2	0.007	0.361	0.402
	Post	280 ± 2 [†]	280 ± 4 [†]			
Free fatty acid, μEq L ⁻¹	Pre	100.4 ± 52.8	94.8 ± 74.0	0.104	0.071	0.204
	Post	207.4 ± 151.5	126.1 ± 61.9			

Values are mean ± standard deviation. ADH: antidiuretic hormone (vasopressin); hANP: human atrial natriuretic peptide.

OSM: osmotic pressure. * $P < 0.05$ between normoxia and hypoxia within the post.

[†] $P < 0.05$ between pre and post within the same condition.

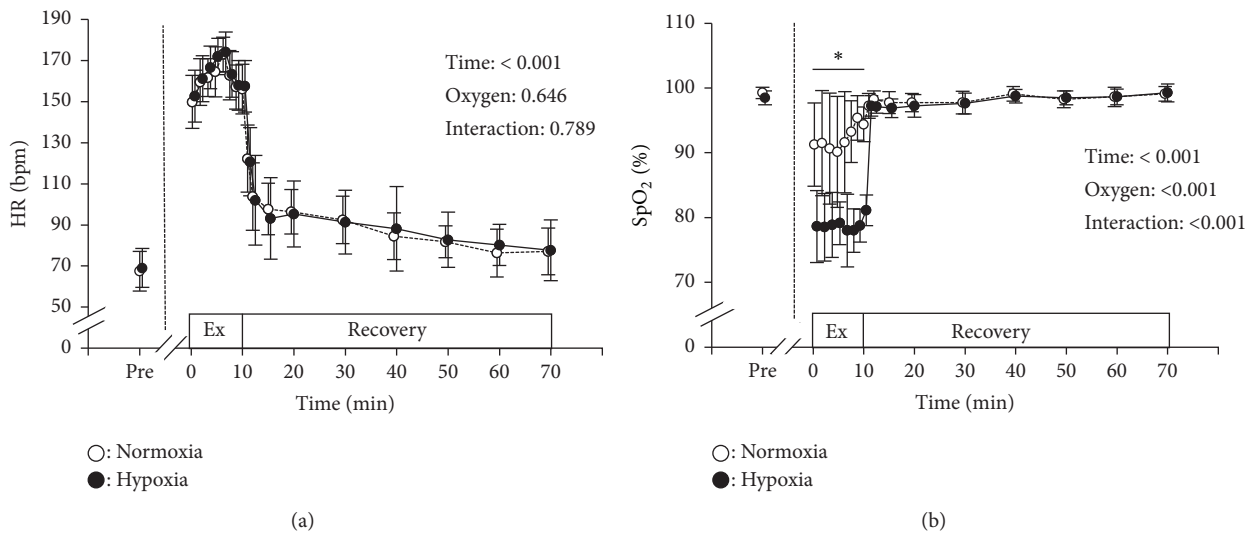


FIGURE 3: Changes in HR (panel (a)) and SpO₂ (panel (b)) at baseline (pre) and during exercise and recovery. Circles indicate the same as in Figure 2. * indicates a significant difference between normoxia and hypoxia within the same time period.

increased fourfold over the pre-exercise values; thereafter, both parameters decreased in accordance with time changes. No significant differences were observed between trials at any point (Figure 4). Summarized results of the statistical analysis [i.e., F values, effect size (partial η^2) and statistical power (1- β)] of the biomarkers and BP variables are shown in Table 2.

Changes in the MAP from the baseline values during recovery were related to the changes in HR from the baseline values during recovery in normoxia when all data were included (6 points during recovery \times 8 participants = 48 plots, Figure 5(a)); however, this correlation was not statistically significant in hypoxia (Figure 5(b)).

4. Discussion

To the best of our knowledge, this is the first study to investigate the influence of resistance exercise under hypoxia on postexercise hemodynamics. The major findings of the present study were threefold: (1) the reductions in BP and the increases in ADH responses during recovery after resistance exercise were greater in hypoxia than in normoxia, (2) the HR responses throughout the study were similar between normoxia and hypoxia, and (3) the changes in HR from the baseline values during the recovery period were associated with the MAP changes in normoxia, but this relationship was not observed in hypoxia. Collectively, these results suggest

TABLE 2: Summarized results of statistical analysis in the subset of outcomes.

	df	F value			Effect size (partial η^2)			Power (1- β)		
		Time	Oxygen	Interaction	Time	Oxygen	Interaction	Time	Oxygen	Interaction
ADH	(1, 7)	8.408	10.365	1.815	0.546	0.597	0.206	0.702	0.788	0.215
Aldosterone	(1, 7)	44.125	0.800	1.066	0.863	0.103	0.132	0.999	0.122	0.146
hANP	(1, 7)	8.262	0.002	0.622	0.541	0.000	0.082	0.695	0.050	0.105
Adenosine	(1, 7)	0.042	1.001	0.704	0.006	0.125	0.091	0.054	0.140	0.113
OSM	(1, 7)	14.044	0.955	0.798	0.667	0.120	0.102	0.893	0.136	0.121
Free fatty acid	(1, 7)	3.495	4.542	1.966	0.333	0.394	0.219	0.366	0.452	0.229
Epinephrine	(3, 21)	18.527	1.327	1.045	0.726	0.159	0.130	1.000	0.170	0.243
Norepinephrine	(3, 21)	92.469	0.035	0.078	0.930	0.005	0.011	1.000	0.053	0.062
SBP	(6, 42)	9.464	3.316	3.761	0.575	0.321	0.350	1.000	0.350	0.933
DBP	(6, 42)	6.451	3.088	2.768	0.480	0.306	0.283	0.997	0.330	0.824
MAP	(6, 42)	8.661	3.629	4.370	0.553	0.341	0.384	1.000	0.377	0.966

df: degree of freedom.

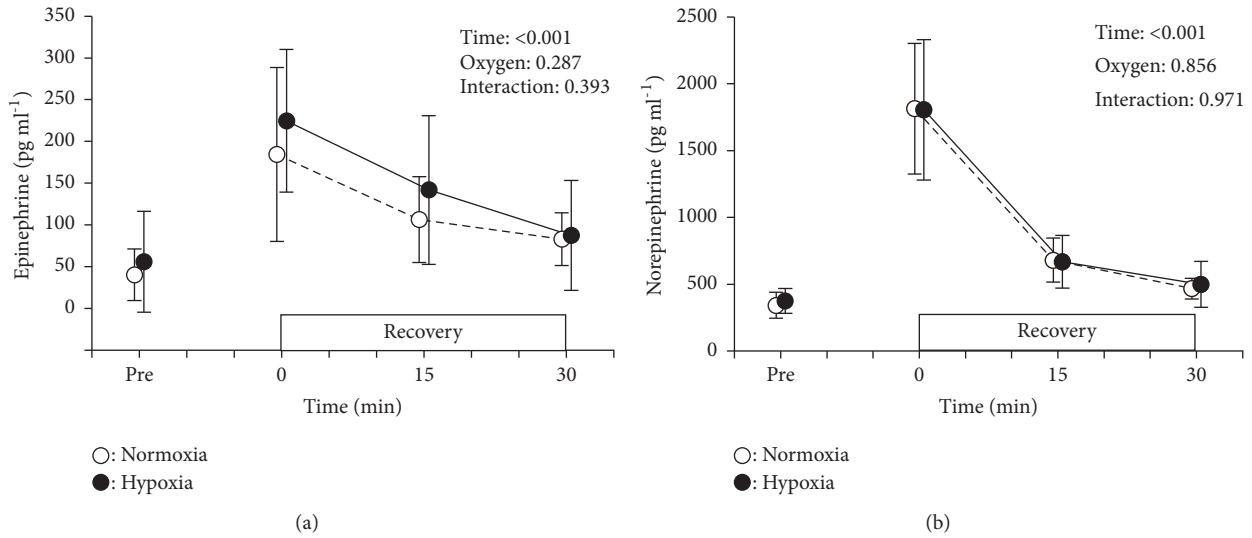


FIGURE 4: Changes in plasma epinephrine (panel (a)) and norepinephrine (panel (b)) at baseline (pre), immediately after resistance exercise (time = 0) and during the first 30 min of recovery. Circles indicate the same as in Figure 2.

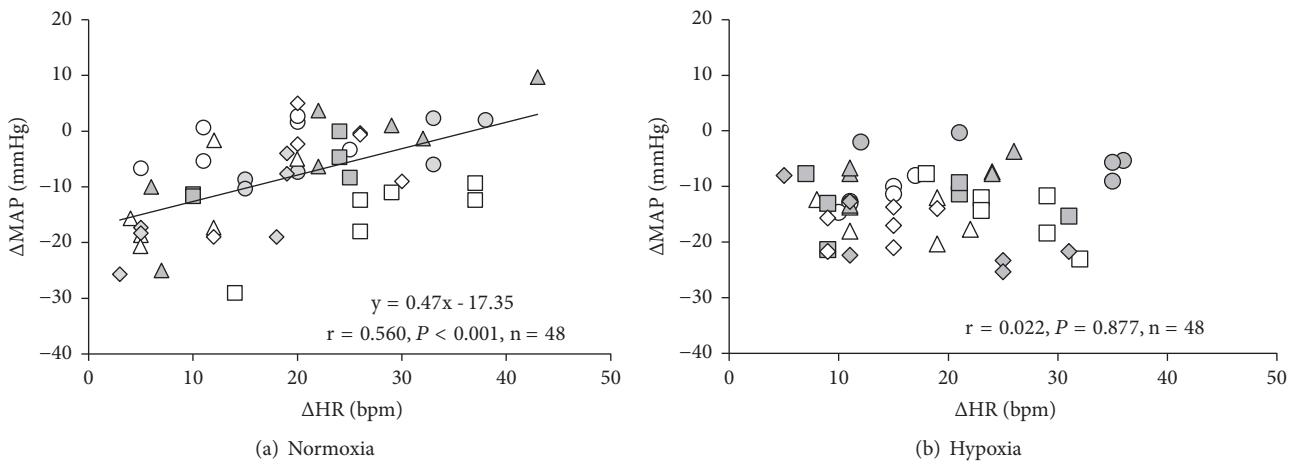


FIGURE 5: Relationship between changes in MAP and HR under normoxia (panel (a)) and hypoxia (panel (b)) when all data points during the recovery period are pooled. The changes in MAP and HR were calculated between the baseline values and each recovery period (10, 20, 30, 40, 50, and 60 min). Different symbols indicate each subject.

that hypoxic resistance exercise caused greater hypotension after exercise and increased in ADH responses. From observing the results of the relation between HR and MAP during recovery periods, the underlying mechanisms of PEH after resistance exercise may be different between normoxia and hypoxia.

Since MAP is a functional product of cardiac output ($HR \times \text{stroke volume [SV]}$) and systemic vascular resistance (SVR), it may at first be reasonable to focus on these two basic components (three parameters). Previous studies have demonstrated controversial findings regarding how these parameters (i.e., cardiac output [CO], SV, and SVR) change after resistance exercise. Some studies found that CO decreased [6, 7, 9, 10], probably due to reductions in SV [7, 9, 10], while one study showed unchanged CO [8]. On the other hand, it was reported that SVR increased [6], remained unchanged [8, 10], or decreased [7] after resistance exercise. Unfortunately, these previous studies were conducted in normoxia and not hypoxia [6–10]; in the present study, we assessed only HR and did not find any differences between trials. Therefore, it is uncertain whether reductions in CO (including SV) and/or SVR caused greater hypotension in hypoxia. However, a previous study reported that there were no differences in HR, SV, and CO between normoxia and hypoxia after exercise [28]. Additionally, it has been reported that endothelial mediated vasodilation was greater in hypoxia than in normoxia after exercise [29]. Although we did not measure blood flow, meaning without parameters of SVR (i.e., MAP/blood flow), there may be a possibility that the greater postexercise hypotension in hypoxia in the present study might be induced by reductions in SVR. It may be worth mentioning that the relationship between the changes in MAP and HR differed between trials despite similar HR responses *per se* in both trials. All the previously mentioned studies above found increases in HR during recovery after resistance exercise, which suggests that this increased HR during the hypotensive period may play an important role in maintaining BP, namely, the prevention of syncope after exercise. A positive relation between these parameters, which was observed in the normoxia trial, may indicate that reductions in MAP are compensated for by a higher HR, while other mechanisms should be considered in the hypoxia trial. Our analysis included all data (i.e., all the subjects and time points); however, interindividual and intraindividual variations should be considered in future studies.

The hypoxia trial led to greater ADH secretion than the normoxia trial. A classic hemodynamics study reported that ADH increased to about two times the pre-exercise level after treadmill walking [30]. Furthermore, it has been reported that acute hypoxic exposure may produce significant hypotension with consequent increased plasma arginine vasopressin (i.e., increased ADH) [31]. Therefore, our results may be partly supported by these studies. In contrast, a subsequent study reported that release of arginine vasopressin was unaffected by hypoxia *per se* (i.e., at resting condition); moreover, arginine vasopressin increased during exercise, and its release was primarily stimulated by increased OSM [32]. Although the study settings of previous studies and the present study were completely different, the results of

OSM in the preset study that showed significant decreases from the prevalues in both normoxia and hypoxia seemed inconsistent. We must acknowledge that measured points were only before exercise and 60 min after exercise and, therefore, further explanation about the relationship among changes in MAP, ADH, and OSM during this longer period (more than 60 min) cannot be obtained at this stage. Another concern is the longer exposure in hypoxia. In the present study, the subjects were exposed to hypoxia for ~90 min (13% FiO_2). Similar long exposure to hypoxia ~60 min (10.5% FiO_2) was present in a previous study [31], while a relatively shorter period of exposure to hypoxia with exercise ~20 min (13% FiO_2) was reported in another study [32]. Therefore, our results indicated that longer exposure to hypoxia could be a secondary effect of hypoxia, including greater release of ADH and greater reductions in BP after resistance exercise that was in the previous study [31]. Nonetheless, we did not find any significant association or causal relationship between changes in the BP and ADH; therefore, future studies that explore this subject are warranted.

With regard to other biomarkers, we obtained confusing findings. Previous hemodynamic studies highlighted the potential role of exaggerated circulating epinephrine levels in syncope under hypoxia [33, 34]. Indeed, fourfold higher epinephrine levels were found at the onset of hypotension in hypoxia [35]. Moreover, exaggerated circulating epinephrine levels may have been linked with skeletal muscle vasodilation and/or vasodilation or splanchnic circulation [36, 37]. In the present study, the epinephrine and norepinephrine levels immediately after exercise were fourfold higher than the baseline values, but there were no statistical differences between normoxia and hypoxia.

One difficulty in interpreting our results against the previous studies is that we did not assess orthostatic tolerance and no subjects claimed (pre) syncope symptoms throughout the study. By contrast, hANP and adenosine, which are potent vasodilators, decreased or remained unchanged and there were no differences between the trials. These may also be difficulties in interpreting the BP responses during recovery in the present study. However, as the circulating half-life of ANP is only 2–3 min, it is questionable whether hANP release may relate to BP responses [38]. In addition, a previous study reported that decreased BP after exercise was not directly related to the release of ANP [39]. It was also reported that adenosine is responsible for vasodilation during the initial phase after ischemic exercise in dogs, but the re-uptake of adenosine is very rapid following exercise [40]. It is well known that the renin–angiotensin–aldosterone system is a hormone system that regulates BP and fluid balance. Briefly, renin is released from the kidneys during low perfusion pressure; thereafter, it converts angiotensin to angiotensin I, followed by angiotensin II, which is a powerful vasoconstrictor. Angiotensin II also stimulates the secretion of the hormone aldosterone [41]. We found significant increases in aldosterone after 60 min of recovery, but there were no differences in the aldosterone levels between the trials. A classic hemodynamic study found that aldosterone levels increased ~twofold at 15 min after exercise [30]. Therefore, although this is highly speculative with regard to the hypotension

period, decreased hANP and increased aldosterone levels may prevent further reductions in BP (i.e., the prevention of syncope).

However, these biomarker results (i.e., epinephrine, norepinephrine, hANP, adenosine, and aldosterone responses) may not account for the different BP regulation between normoxia and hypoxia; therefore, further results are required. Since higher levels of FFA in rats, following acute infusion into the portal vein, mediate the pressor response [42], there may be a possibility that the FFA levels affected the BP response during recovery in the present study. Indeed, a previous study demonstrated that both the FFA and the BP variables increased in parallel after a heparin infusion activated lipoprotein lipase activity and facilitated the turnover of triglycerides to FFAs [43]. In the present study, we found that oxygen, time, and, interaction had no significant effect on the FFA levels; however, the FFA in both trials increased slightly and showed a lower trend in hypoxia 60 min post-recovery. Therefore, our results for BP can be partly explained by previous studies. We must acknowledge that this is also speculative, and we should assess glucose and lipid metabolism directly in future studies.

4.1. Methodological Considerations. There are several limitations in interpreting the results of the present study. First, the relatively small sample size should be considered. Thus, based on our previous study [24], we also conducted post hoc power analysis for pairwise comparisons that were observed with significant differences in variables (i.e., SBP, DBP, MAP, and ADH) as the standard of 80% power with a two-sided significance level of 0.05 (G Power 3.1). We estimated that a sample size of eight would have been necessary to achieve the appropriate statistical power for BP comparisons (SBP at 10 min and 20 min and DBP and MAP at 20 min and 30 min), while 13 subjects would have been required for ADH values postexercise. However, 7 of the 8 subjects showed higher ADH values in hypoxia than in normoxia, and the statistical power was high enough for the BP variables. Although future studies are required, it is unlikely that additional data will strongly affect our conclusions. Second, we recruited only young males in this study. It is therefore uncertain whether our results can be generalized to other populations, such as females and aged people. Similarly, the lack of differences in the physical fitness level of the study subjects should be considered to account for individual differences in future studies. Finally, the precise mechanisms causing greater hypotension after hypoxic resistance exercise than after normoxic resistance exercise are still unclear. We cannot account for this, and therefore the assessment of other potential candidates for influencing BP regulation (e.g., cardiac output, vascular resistance, baroreflex sensitivity, and various vasodilator substances [e.g., nitric oxide, prostaglandins, ATP, and histamine]), alterations in muscle metabolism, and the promotion of angiogenesis may be required in future studies [2, 44].

5. Conclusion

Our results demonstrate that bilateral leg squats in hypoxia elicit greater hypotension during recovery than in normoxia.

Moreover, ADH release was greater during the recovery period in hypoxia than in normoxia. Changes in HR from baseline during recovery from baseline were related to changes in MAP only in normoxia. These results suggest that the higher HR values during recovery may compensate for hypotension only in normoxia; thus, the underlying mechanisms for the attenuation of hypotension after resistance exercise may differ between normoxia and hypoxia. These findings could help explain the increased risk of syncope after resistance exercise at high-altitudes.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declared that there are no conflicts of interest.

Acknowledgments

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Research Article

A Theory-Based Self-Care Intervention with the Application of Health Literacy Strategies in Patients with High Blood Pressure and Limited Health Literacy: A Protocol Study

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The purpose of this study is to assess the effectiveness of a theory-based self-care intervention with the application of health literacy strategies in patients with high blood pressure and limited health literacy. This is a randomized controlled trial, with measurements at baseline and 1 and 3 months follow-up. 100 patients with high blood pressure and limited health literacy will be randomly allocated to either an intervention group or a usual care control group. We will mainly establish the intervention model based on the principal health belief model components. Patients randomized to the intervention group will receive four educational sessions during four weeks. Considering the limited health literacy level of the patients of the study, health literacy strategies will be used in educational material design for enhancing the quality of the intervention. In order to cover these strategies, we will design four standard animated comics and fact sheets with illustrations and photos consistent with the health belief model constructs and educational sessions' topics. Data will be collected using some questionnaires and will be analyzed using the SPSS software. The findings of this study may assist with the development of a theoretical model for self-care intervention in patients with high blood pressure and limited health literacy.

1. Introduction

Hypertension is a chronic condition affecting approximately one billion individuals worldwide [1]. A 24% increase in developed and 80% in developing countries are predicted for the year 2025 and the increase is expected to be much higher than these predictions [2]. In this regard, it was reported to be 14 to 34 percent in Iran [3] and a systematically review study reported high rates of hypertension among males and females globally [4]. This chronic disease can lead to very serious consequences such as cardiovascular and kidney disease [5]. Due to the high prevalence of hypertension and its serious complications, the World Health Organization (WHO) assigned the theme of World Health Day 2013 to hypertension as a "silent killer, global public health crisis" [6].

Despite the benefits of evidence-based hypertension self-care behaviors in improving blood pressure, hypertensive

patients usually have low compliance with the recommended self-care behaviors. Various studies all over the world suggest a high prevalence of uncontrolled blood pressure among people with hypertension [7, 8]. One approach that may advance blood pressure control and be practicable for the most of hypertensive patients is patient compliance with self-care behaviors [9]. The findings of a meta-analysis that examined the results of 87 studies indicated that optimal self-care in hypertensive patients could reduce systolic and diastolic blood pressure by 5 and 4.3 mmHg, respectively [10]. Self-care for people with high blood pressure includes a diet rich in fruits and vegetables, cessation of smoking, sufficient physical activity, antihypertensive medication, reduction in weight, saturated and total fat, and sodium, and moderate alcohol consumption [11]. Despite the benefits of evidence-based hypertension self-care behaviors in improving blood pressure, hypertensive patients generally do not follow medical

or lifestyle recommendations and compliance with self-care behaviors in these patients is not desirable [12].

The WHO has emphasized patient education as an important strategy to improve the active participation of patients in their disease management process [13]. Self-care behaviors are influenced by demographic variables and modifiable psychological variables such as self-efficacy, perceived threats, perceived benefits and barriers [11, 14]. Although some studies have examined educational interventions in patients with high blood pressure, they often lack a theoretical framework describing how the educational emphasis on social, psychological, and cognitive variables can affect self-care behaviors in these patients.

Health Belief Model (HBM) is one of the most important theories of behavior change that have been widely considered in behavioral health sciences and successfully applied in the design of health interventions. This model has emphasized the role of moderating factors (demographic, social, and structural factors) and individual perceptions (perceived sensitivity, perceived severity, perceived benefits, perceived barriers, guidance for action, and self-efficacy) in determining the likelihood of performing a behavior [15]. According to this model, a person's decision and motivation to perform a particular behavior included items such as person's perception of being at risk (perceived susceptibility) and its seriousness (perceived severity), belief in the perceived action of usefulness to reduce the risk of disease, and understanding of the health benefits (perceived benefits) due to obstacles and moderating factors such as demographic and psychosocial variables (awareness) and people's judgments of their capabilities to execute given level of performance (self-efficacy) [16, 17]. The results of a cross-sectional study carried out in an earlier study showed that the HBM and its related structures, especially self-efficacy, perceived susceptibility, and severity of complications, are important determinants of self-care behaviors in hypertensive patients with limited health literacy [18].

Although education and especially the theory or model-based education are effective in controlling the blood pressure of patients, there is some evidence suggesting that limited health literacy of patients could act as a barrier in the result of the interventions [19]. Evidence suggests that limited health literacy patients may understand less than half of what is told to them during medical communication [20]. Moreover, patients with low health literacy may be ashamed by their condition and hide their low level of literacy from healthcare providers who could possibly help [21]. In this regard, the results of a study on diabetic patients showed that despite the fact that 73% of patients with inadequate health literacy participated in diabetes education classes, 50% of them did not know the signs and symptoms of low blood sugar and 62% of them were unaware of the treatment methods for reducing blood glucose [22].

Choosing proper strategies, based on deeper understanding of needs and capabilities of patients with limited health literacy may help healthcare providers to communicate more efficiently with these patients [23]. Although low health literacy patients regularly rely on verbal instructions, they may have difficulty remembering and comprehending

information [24]. Health literacy experts recommend incorporating a few effective and feasible strategies to advance communication and patients' understanding during the communication. Strategies such as plain language and using pictorial media in education will be used in this study.

Regarding high prevalence of hypertension in Iran and limited health literacy among a large population of these patients, it is indispensable to evaluate the effectiveness of an educational intervention based on influencing psychological factors using HBM applying health literacy strategies to promote self-care behaviors in patients with high blood pressure.

2. Material and Methods

2.1. Design. This randomized control trial (RCT) will be conducted with the high blood pressure patients attending to Haft-e-Tir comprehensive health services center of Bushehr, south of Iran. The trial was registered at the Iranian Registry of Clinical Trials with the IRCT code: IRCT2017011731999N1. The participants will be invited to the study to measure their health literacy level at first. Patients who have limited health literacy level according to S-TOFHLA result will be assigned to the two groups: HBM and health literacy strategies-based self-care intervention (trial) and usual care group (control).

2.2. Setting. All patients recruited are those diagnosed with high blood pressure who are referred to Haft-e-Tir comprehensive health services center in Bushehr city (south of Iran) between July 2017 and August 2017.

2.3. Patient Eligibility. The patients will be entered into the study if they are diagnosed with high blood pressure. Inclusion criteria for this study are as follows: (a) passing at least 6 months since the definitive diagnosis of the disease, (b) being able to read, write, and speak Persian, (c) being 30 years old and over, (d) having no severe complications caused by hypertension, including cardiovascular disease, kidney disease, retinal disease, and stroke, and (e) having the desire to participate in the study. Exclusion criteria for the study consist of (a) causing severe complications from hypertension, including cardiovascular disease, kidney disease, retina, and stroke during the study and (b) missing attending educational classes more than once.

2.4. Ethical Consideration. The study protocol will follow the principals of the "Declaration of Helsinki." The participants will be told that they can withdraw from the study at any time and all information will be kept secret and anonymous. This study was approved by Bushehr University of Medical Sciences Ethics Committee (Number IR.BPUMS.REC.1395.128). Informed consent will be obtained from all the participants who will agree to participate in the study.

2.5. Sample Size. According to the study performed by Eftekhar Ardebili et al., 2014 [25], the effect size for the study has obtained based on 90% power, 5 % type one error level, and 1 unit difference between the mean score of knowledge

before and, after the intervention, 40 patient per group have been estimated. Considering a dropout rate of 10% during the study, we aim to recruit 50 patients per group.

2.6. Measurement and Procedure. After checking the medical records file in the Haft-e-Tir comprehensive health services center and invitation of patients who meet the inclusion criteria for the study, invited participants will undergo a screening test by Test of Functional Health Literacy in Adults (S-TOFHLA) [26] for selecting those who have limited health literacy. S-TOFHLA is a valid and widely used measure which takes 12 minutes or less to administer. The S-TOFHLA includes reading comprehension and numeracy sections and uses actual materials that patients might encounter in the healthcare setting, such as medication label instructions. The sum of the 2 sections yields the S-TOFHLA score, which ranges from 0 to 100. Scores on the S-TOFHLA are classified and interpreted as follows: inadequate health literacy (scores 0 to 53): individuals will often misread the simplest materials, including prescription bottles and appointment slips and the instructions for an upper gastrointestinal tract radiograph series; marginal health literacy (scores 54 to 66): individuals perform better on the simplest tasks but have difficulty comprehending the Medicaid rights and responsibilities passage; adequate health literacy (scores 67 to 100): individuals will successfully complete most of the tasks required to function in the healthcare setting, although many still have difficulty comprehending more difficult information (i.e., materials written above a 10th grade reading level). In this study patients with both inadequate and marginal health literacy are considered limited health literacy. The valid Persian version of the scale shows adequate internal reliability for numeracy (Cronbach's $\alpha = 0.69$) and for reading comprehension (Cronbach's $\alpha = 0.78$) [27].

Participants of the study will undergo three measurements: on entry to the study (pretest) and 1 and 3 months after having gone through the intervention for following up. Selected patients will go through the pretest and a then one-month intervention, 1 and 3 months after intervention follow-up.

2.7. Randomization and Blinding. From all hypertensive patients who had medical records in the Haft-e-Tir comprehensive health services center and were eligible for the study, we will select for the invitation by simple random sampling. Then we will screen them for health literacy stage. After completing the inform consent form, limited health literacy patients will randomly allocate to either the control or the intervention group. Randomization of the participants will be done using permuted block randomization. Due to the nature of this intervention, blinding of the patients to the allocation will not be completely possible.

2.8. Outcome Measures. The outcome will be assessed at the baseline, one and 3-month after intervention [Figure 1]. Baseline measurement includes demographic (age, sex, marital status, education, job, income, smoking, and duration of the disease), HBM constructs questionnaire (perceived

susceptibility, perceived severity, perceived barriers, perceived benefits, and self-efficacy), and self-care behaviors questionnaire.

2.9. Primary Outcome Measures

2.9.1. Self-Care Behavior. Self-care behaviors will be determined using the 31-item hypertension self-care activity level effects (H-scale) prepared by Findlow [28]. This scale aims to help physicians for a better guidance to hypertensive patients who are looking for attaining blood pressure control [29]. The H-scale surveys the level of self-care by questioning about the number of days per week on which an individual carries out a self-care behavior. The H-scale was previously validated in Persian patients with high blood pressure [28]. The Persian version consisted of 27 items that measure the hypertension self-care activities with the following domains: medication adherence (3 items), physical activity (2 items), low-salt diet (10 items), smoking (2 items), alcohol (1 item), and weight management (9 items). The Persian version of the scale shows adequate internal consistency. Cronbach alphas were as follows: medication adherence (Cronbach's $\alpha = 0.91$), low-salt diet (Cronbach's $\alpha = 0.72$), physical activity (Cronbach's $\alpha = 0.96$), smoking (Cronbach's $\alpha = 0.91$), and weight management (Cronbach's $\alpha = 0.85$).

2.10. Secondary Outcome

2.10.1. Knowledge of Hypertension. Hypertension knowledge will be assess by using Hypertension Knowledge Level Scale (HK-LS); this 22-item scale is prepared by Erkoç et al. [30]. Hypertension Knowledge Level Scale (HK-LS) will assess respondents' knowledge in defining hypertension, lifestyle, medical treatment, drug compliance, diet, and complications of hypertension. Each item is a full sentence that is either correct or incorrect. And each item is prepared as part of a standard answer (correct, incorrect, or do not know). Motlagh et al. have validated this questionnaire in Iranian population [28]. In Persian version in the validation process, two items were excluded from the scale and the final version has 19 true/false items.

2.10.2. Health Belief Model Constructs. In order to assess the constructs of health belief model, a researcher made the questionnaire that will be used. Items developed for susceptibility, seriousness, benefits, barriers, and self-efficacy focused on self-care behaviors in hypertensive patients. 39 items with 5-point Likert answers will be used. Nine items for perceived benefits, 7 items for perceived barriers, 9 items for perceived susceptibility, 6 items for perceived severity, and 10 items for perceived self-efficacy were written. For determination of content validity, the list items were distributed to judges who were faculty members and PhD candidates and they were quite familiar with HBM constructs. In content validity, altering the format of questions and ignoring irrelevant questions were done. Then, mean Content Validity Index (CVI) and Content Validity Rate (CVR) of the questionnaire were calculated as 0.94 and 0.91, respectively.

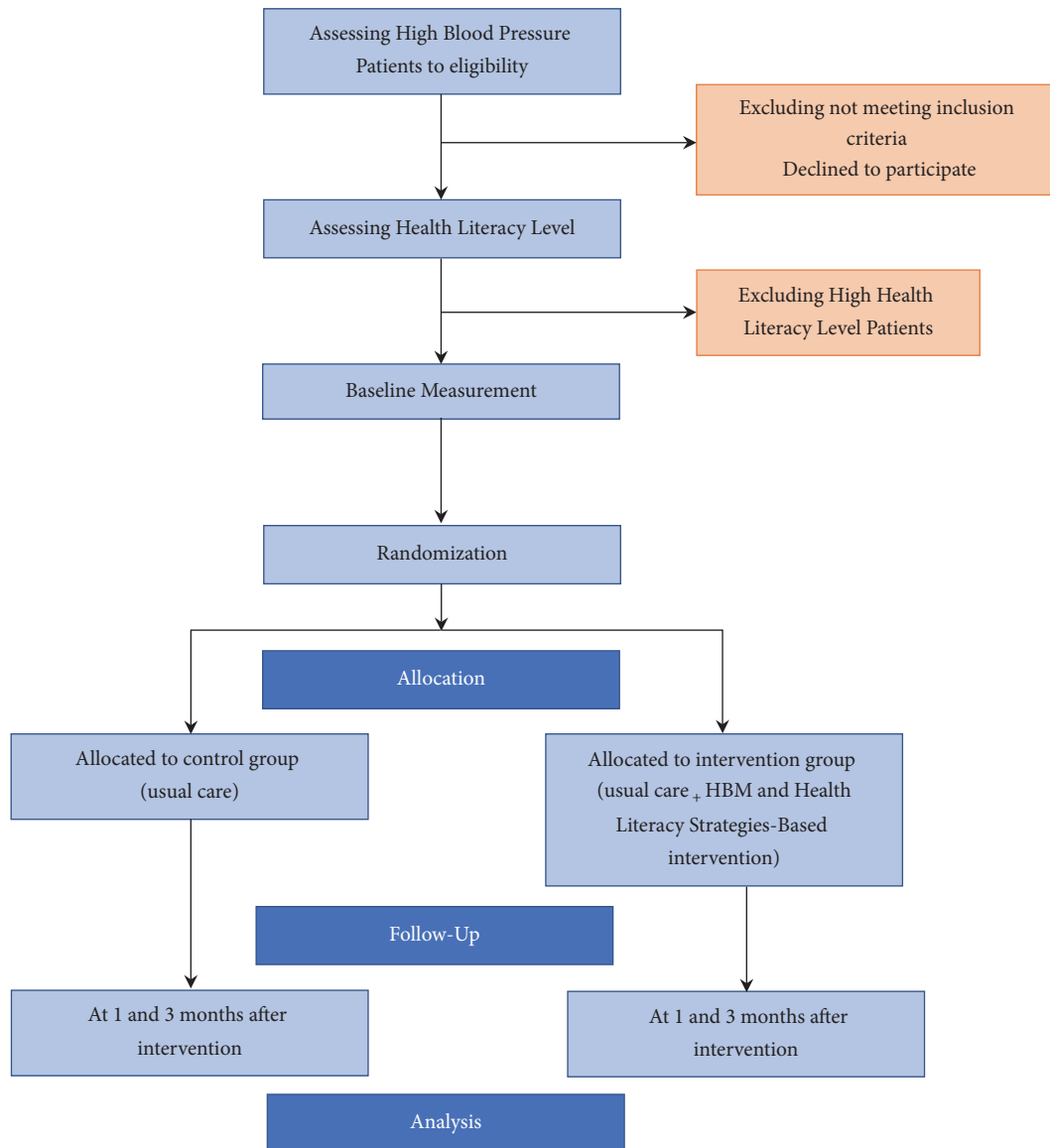


FIGURE 1: Study flow.

Reliability of the scale was calculated and the Cronbach's alpha values of knowledge questions were 0.71, 0.70, 0.70, 0.82, and 0.85 for perceived susceptibility, perceived severity, perceived barriers, perceived benefits, and perceived self-efficacy, respectively.

2.11. Intervention

2.11.1. Theoretical Framework. HBM constructs are the guidelines for the educational intervention design in this study. In the HBM model, perceived severity, perceived benefits, perceived barriers, and perceived self-efficacy are the determinant components. We will mainly establish the intervention model based on the principal HBM components. Patients randomized to the intervention group will receive four groups of educational sessions (lasting 50-60 min)

during four weeks. Topics of the first session are "what is high blood pressure?" and "what is self-care for hypertension?" This session will focus on the strategies to enhance perceived susceptibility and perceived severity of patients toward the disease. In this session, the patients will face the problem (risk of complications of hypertension problems) and they will be threatened (perceived susceptibility). Then, they will understand the depth of the risk and seriousness of complications (perceived severity).

In the second session, patients will learn and discuss healthy diet (such as low salt, low fat, fruit, and vegetable-rich diet). In the third session, patients will learn about physical activity and weight management. The fourth session will focus on medication adherence and avoidance of smoking and alcohol drinking. The importance of self-care behaviors, being physically active, adhering to medication, avoidance of

smoking and alcohol drinking, and also possible barriers to a continuous healthy diet, will be discussed. In this session, brainstorming the possible and trained solutions for those barriers will cover the perceived barriers. By discussing the benefits and useful outcomes of adherence to the self-care behaviors, patients will believe the benefits and possibility of their behaviors (perceived benefits). Introducing an appropriate role model (strategy of vicarious experiences [Mrs. Karimi]) in video comics, providing solutions to address possible obstacles in removing the barriers, and giving verbal persuasions to positive expressions of the patients were used to enhance the self-efficacy of individuals for self-care behaviors.

Considering the limited health literacy level of the patients of the study, health literacy strategies will be used in educational material design for enhancing the quality of intervention. In order to cover these strategies, we will use four animated comics and fact sheets with a lot of illustrations and photos which are consistent with the HBM constructs and educational sessions' topics. Animated comics will be produced as media that will be shown to the intervention group patients at the beginning of each educational session to help them start discussing the topic and learn more about the self-care throughout the story of them.

In order to design these animated comics, the research team defines the characters of the story of a hypertensive patient (Mrs. Karimi), her family and friends and also her physician. The story of each part of the comic will cover the topic of the respective educational session. In the scenario of the animated comics we will make some recommendations for self-care behaviors to hypertensive patients. In the next step, the research team will design the storyboard of each part of the animated comic and then the characters and backgrounds will be illustrated compatible with the culture of the patients of the study using Adobe Illustrator software by a graphic designer. At last, the sounding and animating of each part of the storyboard will be done using Adobe After Effect software by an animation team.

The fact sheets that contain the most important recommendations and reminders of the educational topic will be designed based on existing standards and guidelines for designing simple and comprehensible educational media for limited health literacy patients, such as Simply-Put [31], which is provided by the Center for Disease Prevention and Control as a comprehensive guide for designing simple, understandable media. For optimal comprehension and compliance, it is suggested that patients' educational materials will be written at a sixth-grade or lower reading level, preferably including pictures and illustrations [32]. Therefore, Gunning Fog Index will be used to assess the readability of these written materials. This formula determines how difficult it is to read and understand a piece of writing. Readability will be calculated by the following formula: $GFI = [(number\ of\ words/number\ of\ sentences) + number\ of\ "difficult\ words"] \times 0.4$ [33]. The number that results from the following calculation correlates with the grade level. All the sentences will design and modify in such a way that based on this indicator, scores less than 6 will be obtained for the readability level [32]. Each designed fact sheet will be given to the

intervention group patients at the end of each educational session.

2.12. Statistical Analysis. Survey data will be coded and analyzed using the Statistical Package for the Social Sciences (SPSS) version 22. In addition to providing descriptive statistics, Chi-square test will be used to compare the distribution of qualitative demographical characteristics between the two groups before intervention. T-test will be used to compare the mean scores of knowledge and health belief model constructs (perceived sensitivity, severity perceived benefits, perceived barriers, and perceived self-efficacy) between the two groups. The Repeated Measure ANOVA analysis will be used to examine and compare changes in the mean scores of knowledge and constructs during the study period in each group and the comparison between the two groups. The post hoc analysis will perform within per groups to compare the times. The Kolmogorov-Smirnov test will be used for checking the normality distribution of the data. The P value of <0.05 will be considered statistically significant.

3. Discussion

The purpose of this study is to assess the effectiveness of a theory-based (HBM-based) self-care intervention by the use of health literacy strategies in limited health literacy hypertensive patients. To our knowledge, there is no published study investigating the use of behavioral change theories and health literacy strategies simultaneously to design an intervention to improve self-care in patients with high blood pressure. This protocol has the potential to improve the standard care of patients with limited health literacy by a simple, accessible, and relatively inexpensive way that could improve signs and symptoms. It is hoped that such educational intervention will produce more favorable health outcomes.

In this study the intervention will be based on health belief model. Applying this model would decrease methodological errors of the study which, in turn, would allow us to apply the valid and reliable educational strategies. Consequently, we are likely to believe that designing this educational program based on HBM constructs would be the key to the possible success. If it is found that the intervention improves self-care behaviors, future experimental works will be required to identify the most important component of HBM-based intervention for hypertensive patients. The results of this study will provide useful insights into the role that health literacy strategies, and health literacy level can play a role in improving self-care and awareness of complications in hypertensive patients with limited health literacy. If successful, the intervention may be adopted in other patient populations and RCT study designs.

The proposed study has a number of potential limitations. First, there is only a limited time in which the participants can be recruited. Second, due to the nature of this intervention, blinding of the patients to the allocation is not completely possible in this study. Third, using self-report instruments for measuring self-care behaviors and adherence limits the ability to identify changes objectively. The fourth limitation

is the use of questionnaires that their construct validity was not confirmed due to time limitation. However, appropriate content validity and reliability of the HBM questionnaires were properly met. Further studies should be done to measure long-term effects of the intervention as well as clinical outcomes.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Review Article

Beneficial Role of Mg^{2+} in Prevention and Treatment of Hypertension

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Hypertension constitutes one of the most widespread pathological conditions in developed and developing countries. Currently, more than 1 billion people worldwide are affected by the condition, either as frank hypertension or as prehypertension, raising the risk for major long-term complications and life-threatening pathologies. The costs in terms of health care services, medications for the treatment of hypertension and its complications, and associated loss in productivity represent a major economic burden for the various countries. The necessity of developing treatments that are economically more sustainable and with better compliance has been increasing alongside the incidence of the pathology. Along these lines, attention has been paid to the implementation of affordable but nutritious diets that deliver appropriate levels of macro- and micronutrients as integral part of the diets themselves or as supplements. In particular, experimental and clinical evidence suggests that an appropriate intake of dietary magnesium can be beneficial in controlling blood pressure. Additional advantages of a more diffuse therapeutic and/or preventive utilization of magnesium supplements are the virtual absence of side-effects and their affordable costs. The present review will attempt to frame our knowledge of how magnesium exerts its beneficial effects on blood pressure maintenance, which may lead to the development of more effective treatments of hypertension and its main complications.

1. Introduction

Hypertension represents one of the most common human pathological conditions diagnosed. According to data published in 2013 by the World Health Organization, approximately 1.2 billion people worldwide are affected by the pathology [1], irrespective of developed or developing countries, ethnicity, gender, and age. Consistent with this trend, nearly one-third (>29% or 75 millions) of the American adult population is affected by hypertension, defined as high blood pressure [2], and another third presents with prehypertensive state [2], whereby blood pressure values are higher than normal but not yet in the high blood pressure range. More worrisome, only half of the individual with frank hypertension have their condition under medical control [2], raising the risk for the occurrence of life-threatening cardiovascular complications including stroke, myocardial infarction, and aortic aneurysm. This situation is in addition to increased risk of mortality or poor quality of life of the

remaining half of the affected individuals. In terms of age and gender-related distribution, males are more affected than females as young adult [1, 2]. This gender disparity disappears during adulthood, with males and females becoming equally affected, before switching in the other direction in individuals older than 65 y.o., when females become more affected than males [1, 2]. The reasons for this gender-related change in incidence with age are not completely understood, with loss of estrogen-based cardiovascular protection in females among the proposed hypotheses [1].

The etiology of hypertension is also complex spanning from endocrinopathies with abnormally elevated levels of one of the various pressure-controlling hormones (e.g., catecholamine, renin-angiotensin II-aldosterone axis, cortisol, and growth hormone) [3], to renal pathologies (e.g., Bartter's syndrome and Gitelman's syndrome), to primary cardiac hypertrophy, to conditions in which a clear cause-effect relationship cannot be established (idiopathic hypertension). Accordingly, the pharmacological treatment of hypertension

is multifaceted and based primarily on decreasing the circulating volume through the use of diuretics (e.g., furosemide, hydrochloro-thiazide, or amiloride) that inhibit different Na^+ reabsorbing mechanisms in different portions of the nephron. Often, diuretic treatment is used in conjunction with angiotensin-converting-enzyme inhibitors (ACE inhibitors), Ca^{2+} channel blockers, or beta-blockers to regulate cardiac output, rate, and contraction and α 1-adrenergic receptor blockers to control the tone of peripheral resistances, to surgical treatment to remove hormone hypersecreting adenomas, and to better address the underlying mechanism(s) responsible for the sustained increased in blood pressure [3, 4].

The complexity of hypertensive treatment and patient's compliance and responsiveness, however, result in significant costs for the health care system, without the guarantee of an effective medical control of the pathology. Consequently, the need for effective treatments that are economically more affordable and easy to comply with has increased progressively with the raising incidence of hypertension. Interest has shifted towards the implementation of diets that, while being affordable and easy to follow, do provide appropriate levels of macro- and micronutrients, and natural products (e.g., flavonoids) that can help in better controlling blood pressure and associated damaging processes such as oxidative stress.

In this regard, experimental and clinical evidence suggests that an appropriate intake of dietary magnesium can be beneficial in controlling blood pressure. Conceptually, intake of magnesium through the diet or as a supplement has the advantage of being a natural and required element for our cellular composition, of having virtual absence of side-effects, and being financially more affordable than other therapeutic agents, especially in developing countries. Practically, however, the utilization of magnesium in the context of hypertension is still plagued by limited understanding of its true beneficial effects, limited bioavailability of some magnesium supplements, and the general misconception that because magnesium is abundantly present in our body and readily available through diet, the occurrence of magnesium deficiency is a rather rare condition.

In line with the nonpharmacological intent of this monographic issue, the present review will attempt to provide the necessary framework to understand the relevance of physiological magnesium levels for whole body well-being and for a better regulation of blood pressure.

2. Magnesium: Cellular Homeostasis and Transport

Magnesium is the fourth most abundant cation in the human body and the second most abundant intracellular cation after potassium [5]. Within the cell, magnesium ions (Mg^{2+}) are highly compartmentalized within nucleus, mitochondria, endoplasmic and sarcoplasmic reticulum, cytoplasm, and possibly other organelles, although the assessment in the latter has been hampered by technical limitations [5]. Total Mg^{2+} concentrations in excess of 16-18 mM have been measured by a variety of approaches in each of the mentioned compartments [6], with the exception of cytoplasm where

4-5 mM Mg^{2+} is present in the form of a complex with ATP and other phosphonucleotides and between 0.8 and 1 mM is in the free form [6]. Magnesium ions regulate a broad variety of physiological functions, including Ca^{2+} channels, metabolomic receptors, ATPases, cell cycle, MAPKs, IP_3 receptor, insulin signaling, and glucose transport and utilization, just to mention a few [5, 6]. At the cellular level and in the whole body, physiological Mg^{2+} contents are regulated through a series of extrusion and entry mechanisms, the operation of which is tightly controlled by a variety of hormones [5, 6]. Extrusion is mostly accomplished through a $\text{Na}^+/\text{Mg}^{2+}$ exchanger (Slc41A1) activated via cAMP-dependent-phosphorylation, which electrogenically transports $1\text{Na}^+_{\text{in}}:1\text{Mg}^{2+}_{\text{out}}$ [5, 6]. Catecholamine, glucagon, and other cAMP-elevating hormones all promote Mg^{2+} extrusion in exchange for Na^+ [7]. Supporting the importance of the Na^+ electrochemical gradient in favoring Mg^{2+} extrusion, amiloride and other inhibitors of Na^+ transport all inhibit Mg^{2+} extrusion through this exchanger [5-7]. Under conditions in which Na^+ transport is inhibited, an alternative, less efficient, Na^+ -independent Mg^{2+} extrusion pathway becomes operative. This pathway is less well characterized, and not much is known about its activation, implying the possibility that different cells utilize different Na^+ -independent paths to maintain a basal level of Mg^{2+} extrusion [6, 7]. Entry of Mg^{2+} into the cell is accomplished through the operation of two distinct channels, termed TRPM6 and TRPM7 [5, 6]. While TRPM7 is ubiquitously expressed in eukaryotic cells, TRPM6 is more highly expressed in the distal convoluted tubule of the nephron and in the descending colon, i.e., in locations where it can better control renal reabsorption and intestinal absorption to maintain whole body Mg^{2+} levels [5, 6]. Both these channels are maintained in the closed state by the binding of RACK1 at a specific site of the C-terminus [6]. Hormones or agents that activate protein kinase C within the cell can then scavenge RACK1 away from the channels, activating them [6]. Adding to the complexity of these channels, both TRPM6 and TRPM7 possess a α -kinase at their C-terminus, which becomes operative following Mg^{2+} entry and phosphorylates Ser and Thr residues in an alpha-helix loop [6]. Currently, only a handful of targets phosphorylated by these kinases have been identified [5, 6], *de facto* limiting our understanding of the role these kinases play in terms of whole cell function.

Because ~99% of Mg^{2+} is localized intracellularly in bones in soft tissue and ~1% is present in the circulation in both free (approximately 2/3) and bound (~1/3) form, changes in circulating Mg^{2+} levels cannot properly reflect the cellular status of the cation. Consequently, Mg^{2+} insufficiency or deficiency cannot be established using serum Mg^{2+} levels alone [5, 8], but assessment of urinary and intracellular Mg^{2+} levels should be included. Mg^{2+} deficiency, in fact, can be retrospectively identified based on the occurrence of an inverse relationship between the amount of Mg^{2+} eliminated through the urine and the amount of Mg^{2+} intake, and the variation in cellular Mg^{2+} content in more accessible pools such as red blood cells [8].

2.1. Dietary Mg^{2+} Levels and Intake. At the dietary level, Mg^{2+} is present in elevated content in green-leaf vegetables, whole grains, white potatoes, nuts, and legumes [9]. The current RDA (recommended dietary allowance) for magnesium ranges from 240 to 420 mg/day for males 31 to 70 y.o. and ~320 mg/d for females of comparable age range [10]. However, evidence is there indicating that ~60% of the US population does not consume the RDA for magnesium [11] and it is therefore considered to be magnesium insufficient if not frankly deficient. This assessment is supported by similar reports out of UK, Australia, Canada, and other industrialized countries [5], and the observation that dietary Mg^{2+} intake has declined by at least ~40% in the last 4 decades due to changes in food harvesting and processing, water purification, and overall dietary habits [12]. As a dietary supplement, magnesium is most commonly found as MgO (magnesium oxide). Other forms of mineral salts of Mg^{2+} supplements include $Mg(OH)_2$ (magnesium hydroxide), magnesium bicarbonate, carbonate, phosphate, and sulfate. Alternatively, Mg^{2+} can be provided as an organic salt (bound to aspartate, citrate, gluconate, ascorbate, etc.) or chelated with amino acids [12]. While produced at a very low cost, several of the mineral salts of Mg^{2+} have a poor bioavailability (e.g., as low as 4% for magnesium oxide) [12], which greatly limit their effectiveness.

A certain level of magnesium deficiency has been reported in several chronic diseases including hypertension, diabetes, and metabolic syndrome [5]. Yet, it is undetermined whether magnesium deficiency precedes and perhaps contributes to the onset of the disease or is instead the result of the pathology. Irrespective of the time of appearance, however, due to its involvement in a broad range of cellular and physiological functions, magnesium insufficiency or deficiency can impair to a varying extent several of these functions and aggravates the progression of the pathology and its complications.

3. Magnesium and Hypertension

Several lines of evidence suggest a role of Mg^{2+} in inversely regulating blood pressure. Studies carried out in *in vitro* and *in vivo* models in the late 1940s or early 1950s first suggested a role of circulating Mg^{2+} in inhibiting catecholamine release from both peripheral and adrenal sources [13, 14]. Later studies validated these results and showed that infusion of Mg^{2+} significantly reduces the catecholamine-induced increases in systemic vascular resistance, systolic blood pressure, and diastolic blood pressure in a dose-dependent manner and increases coronary blood flow [reviewed in [15]].

A modulating effect of Mg^{2+} on vascular tone and reactivity, and consequently on blood pressure, is in line with the clinical observation that Mg^{2+} infusion decreases peripheral vascular resistance and blood pressure and can induce hypotension through vasodilatation [16, 17]. Increasing extracellular Mg^{2+} concentration promotes vasodilation, thereby increasing blood flow systemically and attenuates agonist-induced vasoconstriction [18, 19]. Conversely, decreasing extracellular Mg^{2+} concentration increases vascular tone and agonist-induced vasoconstriction [20, 21]. The exact

mechanism behind these effects is not completely clear. Because Mg^{2+} acts as a natural Ca^{2+} -channel blocker [15], it is conceivable that physiological extracellular Mg^{2+} concentrations would limit Ca^{2+} entry through the cell membrane and the increase in intracellular $[Ca^{2+}]_i$ necessary for smooth muscle cells contraction and endocrine-regulated increase in vascular tone. Alternatively, owing to the involvement of extra- and intracellular Mg^{2+} in modulating a variety of signaling pathways [5–8], it is possible that an increase and a decrease in cellular Mg^{2+} concentrations can have major opposite implications for smooth muscle cells contraction and relaxation, whereby influencing vascular tone and blood pressure.

The effects of Mg^{2+} are not limited to vascular tone but influence vascular endothelial functions as well [22]. The vascular endothelium regulates vessel tone by releasing nitric oxide, endothelin-1, and prostacyclin PGI_2 [22]. Magnesium ions have been reported to stimulate directly prostacyclin and nitric oxide production [23–25]. In addition, an inverse relationship between the levels of Mg^{2+} and endothelin-1 has been reported [26], further emphasizing the ability of magnesium to modulate vasodilatation through endothelium-dependent and independent mechanisms. A third possible mechanism whereby Mg^{2+} can modulate vascular tone and blood pressure is through its antioxidant and anti-inflammatory effects [27, 28]. Production of reactive oxygen species (ROS) and oxidative stress can be elevated in vascular smooth muscle cells, increasing vasoconstriction [29]. Conversely, the presence of physiological concentrations of Mg^{2+} would reduce ROS formation and antagonize the vasoconstriction effect. How exactly Mg^{2+} exerts this effect is not fully elucidated. Recently, Kolisek and collaborators [30] have hypothesized that the inverse relationship between ROS and Mg^{2+} levels is regulated through PARK7/DJ-1. This protein has antioxidant properties and tightly regulates cellular redox homeostasis. In addition, through androgen receptor activation, it would modulate the expression of SLC41A1, the main exchange mechanism responsible for Mg^{2+} extrusion in mammalian cells (see section on Magnesium: Cellular Homeostasis and Transport).

3.1. Is There a Role for Mg^{2+} in Controlling Hypertension in Human Patients? Epidemiologic studies indicate that the consumption of “hard water” with high levels of magnesium is cardioprotective whereas consumption of “soft water” (i.e., water low in minerals including magnesium) is associated with hypertension and overall higher incidence of cardiovascular diseases. This inverse association was first observed by Joffres et al. in their Honolulu Heart study [31] and subsequently confirmed by other clinical studies [32, 33]. In particular, inverse relationship between magnesium levels and systolic and diastolic pressure values [32] and risk of death from hypertension [33] have been reported, in line with a similar inverse relationship between Mg^{2+} levels and circulating renin concentrations [34] and stiffened blood vessels [35].

The presence of an inverse relationship between circulating Mg^{2+} levels and the detected concentrations of

endothelin-1, PGI₂, ROS, NO, or renin, or systolic and diastolic blood pressure values, however, leaves unanswered the question as to whether magnesium supplementation can be therapeutic in restoring physiological and age-appropriate pressure values. In other words, are magnesium levels prophylactic, or they can also be therapeutic? The attempts to address this question have resulted in contradicting results, and only more recent studies appear to confirm beneficial therapeutic responses following administration of Mg²⁺ salts. The meta-analysis conducted by Dickinson and collaborators [36] assessed retrospectively 12 randomized controlled trials and indicates that diastolic pressure but not systolic pressure decreased to a significant extent as a result of magnesium supplementation [36]. Because of the limited quality of the trials included in the meta-analysis, however, the conclusion of the authors was that a causal association between magnesium supplementation and the decrease in blood pressure was weak, due to inherent bias [36]. More recently, the group of Kass has conducted a similar meta-analysis on more current studies. Twenty-two (22) trials with 23 sets of data were used, for a total of 1173 patients. While the majority of the studies assessed by Dickinson's group lasted for about 8 weeks, the studies analyzed by the group of Kass lasted anywhere from 3 to 24 weeks, with doses of Mg²⁺ ranging from 120 to ~970 mg/d [37]. The conclusion of this study was that higher doses of magnesium produced greater reduction in blood pressure, both systolic and diastolic values [37]. Similar conclusions have been attained more recently by Zhang and collaborators [38]. For their meta-analysis, this latter group assessed 34 trials involving more than 2000 participants, and magnesium supplementation (including a broad array of mineral and organic salts) ranged from 240 to 960 mg/d [38].

Based on these more recent studies [37, 38], it would appear that magnesium supplementation does achieve a statistical significant reduction in blood pressure, both systolic and diastolic values. It has to be noted that the reduction, while significant, ranges between 2 and 4 mmHg for either parameter. In clinical terms, it could be argued that such a reduction is rather small when compared to that attainable with other pharmacological treatments. Also, the presence of some variability in pressure reduction might imply that specific subgroups of patients are more (or less) magnesium-sensitive and therefore more prone to the beneficial effects of magnesium supplementation [37, 38]. At a first glance, it would appear that subgroups with higher magnesium sensitivity include patients of African descent, obese patients, patients with metabolic syndrome (see below) or preeclampsia (see also below), and patients with severe or malignant forms of hypertension [34–38]. Because our understanding of the mechanisms involved in controlling magnesium homeostasis and transport at the level of the cell and the whole body is still incomplete, it cannot be excluded that the “genetics” of magnesium homeostasis, alongside with diet composition, can be major factors in explaining this sensitivity and the effectiveness of magnesium supplementation.

3.2. Magnesium and Stroke. Cerebral insults (strokes) represent one of the most common, and feared, complications of hypertension, as they can result in paralysis, inability to

speak, and difficulty in swallowing (with associated malnutrition) when they do not cause the immediate death of the patients. Strokes result from severe, not-controlled hypertension, affect ~800,000 new patients every year, and are responsible for ~140,000 deaths/year in the US alone [39]. Because of the association of this pathology with hypertension and the potential beneficial effect of magnesium supplementation in controlling hypertension, attention has been paid to the possibility that magnesium supplementation can indeed attenuate the incidence of stroke and/or their outcome. A meta-analysis study conducted by Larsson et al. [40] identified 7 prospective studies that could be used based on their criteria out of 163 articles screened. While the number of studies incorporated in the meta-analysis could be considered relatively small when compared to the starting number of articles screened, it did account for almost 6500 cases of stroke in a pool of participants of more than 240,000. The conclusion of the meta-analysis indicates once again the presence of a statistically significant inverse association between magnesium intake and risk of stroke. According to the study, an increment in magnesium intake of 100 mg/d correlates with an 8% reduction in the risk of stroke. Interestingly, this correlation applies only to ischemic strokes and not to hemorrhagic strokes [40]. While a causal relationship could not be fully validated, it is worth noting that Han and collaborators have recently reported a 5% reduction in the risk of hypertension for a similar (100mg/d) increment in magnesium intake [41].

4. Magnesium and Metabolic Syndrome

The incidence of metabolic syndrome in the human population shows a trend similar to that of hypertension, affecting more than 500 million people worldwide [42]. Haller was the first to introduce the term in 1977 to describe a pathological condition characterized by the association of obesity, diabetes mellitus, hyperlipoproteinemia, hyperuricemia, and hepatic steatosis [43]. Currently, the pathology is diagnosed based on the presence of at least 3 of the following 5 criteria: (1) central obesity (waist circumference ≥ 102 cm or 40 inches for males, and ≥ 88 cm or 35 inches for females); (2) hypertriglyceridemia (TG ≥ 1.7 mmol/L or 150 mg/dl); (3) dyslipidemia (HDL-C < 40 mg/dL for males, and < 50 mg/dL for females) with slightly or markedly elevated total cholesterol and LDL; (4) blood pressure ≥ 130/85 mmHg (or treated for hypertension); and (5) fasting plasma glucose ≥ 6.1 mmol/L (110 mg/dl) [44].

As mentioned above, an increase in systolic and diastolic blood pressure values represents one of the diagnostic criteria for this condition. Hypomagnesemia [45] and intracellular magnesium deficiency [46] are also common features of the pathology. The cause(s) for the onset of metabolic syndrome are not elucidated: for a period of time, the condition was termed Syndrome X to highlight its obscure etiology. Because of the altered triglyceride and cholesterol profiles and the presence of slightly elevated glycemia, the metabolic syndrome is currently considered the result of incipient insulin resistance [44], and progression towards type-2 diabetes mellitus is a typical complication of the

syndrome [47]. Because insulin favors Mg^{2+} accumulation within cells [5, 6], reduced cellular Mg^{2+} levels in the context of insulin resistance are to be expected. According to the CARDIA study, a magnesium enriched diet or magnesium supplementation appear effective in reducing the risk of metabolic syndrome and its progression towards diabetes and cardiovascular complications [48].

5. Magnesium and Preeclampsia

The term preeclampsia refers to a clinical disorder during pregnancy characterized by hypertension after 20 weeks of gestation, with marked proteinuria [49]. The disorder affects about 5% of delivery and when left untreated it develops into eclampsia, with occurrence of tonic-clonic seizures for about 1 min, followed by a period of confusion or coma [49, 50]. Major complications of eclampsia are as follows: aspiration pneumonia, cerebral hemorrhage, kidney failure, and cardiac arrest [50]. Eclampsia affects about 1.5% or all the deliveries, with a mortality rate around 1% of all the affected women [50]. In 2015, the last year for which we have reliable collected data, eclampsia accounted to ~47,000 deaths in the world [51].

Magnesium sulfate constitutes the treatment of choice for the prevention of preeclampsia related convulsions. The first report of its effectiveness was by Pritchard in 1955 [52]. As its anticonvulsion use became more common and accepted [53], administration of magnesium sulfate has been observed to result in better outcome than other anticonvulsive (e.g., diazepam) [54]. Anticonvulsive drugs such as diazepam or phenytoin [53, 54] are still used for the treatment of eclampsia as coadjuvants of magnesium sulfate treatment. The addition of these therapeutic agents helps in maintaining magnesium dosage and circulating magnesium levels in an optimal therapeutic range, thus preventing magnesium-related toxic side-effects such as paralysis of maternal thoracic muscles and respiratory depression, which could occur at high doses of magnesium sulfate if this was the only therapeutic agent used [53]

Treatment of preeclampsia with magnesium sulfate has been reported to improve endothelial function. This improvement can be due to the previously described beneficial effects of magnesium on vascular tone (e.g., reduced stiffness and reduced Ca^{2+} entry), vascular responsiveness to endothelin-1, renin, and ROS production, and overall vascular function, including increased nitric oxide and PGI_2 production, which promote vasodilation and inhibit platelet aggregation, respectively [23–26]. Yet, it still remains controversial whether women undergoing preeclampsia have lower than normal circulating levels of Mg^{2+} and therefore are more exposed to the vascular irregularities and hypertone prevented by Mg^{2+} . Some studies have indeed reported decreased serum and intracellular Mg^{2+} levels [55, 56] whereas other studies have failed to identify similar differences between preeclamptic and healthy gravidas [57, 58]. Also in this clinical scenario, the reason(s) for such a discrepancy is/are not apparent, although patients' heterogeneity and perhaps dietary intake are possible confounders.

Despite the inconsistency in basal serum and cellular Mg^{2+} levels between healthy women and women with

preeclampsia, observation by Standley and collaborators suggests that magnesium levels can still be used as a predictive/prognostic tool [59]. In studying magnesium levels at different gestational ages, this group observed that the levels of the cation decrease in both preeclamptic and healthy pregnancies, but the decrease in preeclamptic women occurs at an earlier stage as compared to the healthy counterparts and could therefore be utilized as a marker of severity of the pathology [59].

6. Conclusions and Perspectives

In this review, we have attempted to provide a general understanding of how human cells control cellular and circulating magnesium levels, the importance of these levels for wellness in general and blood pressure levels in particular, and how diet and dietary supplements can be utilized effectively to maintain physiological levels of magnesium. We have also attempted to provide an appreciation of the complexity surrounding the prophylactic and possibly therapeutic use of magnesium supplementation in hypertension, and hypertension-associated pathologies such as stroke, metabolic syndrome, and preeclampsia/eclampsia.

Despite the inherent difficulty to provide a clear cut approach and validity to the use of magnesium supplementation as a therapeutic tool, it is apparent from our reviewing of the mentioned pathologies that magnesium supplementation does have a role as a coadjuvant of more established pharmacological tools currently utilized in the various fields. The low cost of production and the virtual absence of side-effects in the normal range of doses more commonly utilized (e.g., up to 960 mg/day) add to the “appeal” of a routine use of this mineral as a dietary supplement, especially in areas where health care costs, availability of more expensive drugs, and ultimately compliance of the patients to a given therapeutic protocol represent critical factors hampering the effectiveness of medical intervention.

Conflicts of Interest

The author has no knowledge of any conflicts of interest.

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Research Article

Designing a Cocreated Intervention with African American Older Adults for Hypertension Self-Management

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Hypertension is a lifelong disease that requires self-management. Additionally, there are disparities in hypertension self-management that disproportionately affect African Americans. Interventions designed in collaboration with older adults have the potential to improve hypertension self-management. The purpose of this design paper is to describe the process in which African American older adults and nurse researchers cocreated an intervention to address stress in the self-management of hypertension. A semistructured interview guide was used to elicit feedback on self-management behaviors to cocreate an intervention with the participants. Participants provided constant iterative feedback on the design used for the intervention. Participants prioritized the content and mode of delivery. African American older adults with hypertension ($N = 31$; 87% women) participated in two focus group sessions. The primary stressors identified by the group that influenced their blood pressure self-management were as follows: (a) measuring blood pressure and using home blood pressure monitors; (b) difficulty communicating with family and friends; (c) sleep management and pain at night; and (d) healthy eating. Based on the participants' feedback, we created four biweekly (2-hour) group sessions that incorporated their suggestions and addressed their concerns. Health care providers can use this technique to engage African American older adults in participant-centered hypertension self-management.

1. Introduction

Hypertension self-management is complex, particularly among older African American individuals who are affected by additional factors. These factors that are thought to contribute to disparities in hypertension include low self-efficacy, limited social support, increased stress due to racism or discrimination, and perceived lack of control over whether or not one will develop hypertension [1–3]. In addition, socioeconomic disadvantages (i.e., low income, low education, and neighborhood safety) [3, 4] increase the cumulative stressors that African Americans experience and contribute to acute and chronic stress responses that interfere with self-management and produce poor health outcomes [3, 5].

Hypertension self-management includes taking prescribed medications as directed, managing daily stress, eating a balanced diet, and performing regular physical activity, each of these is associated with improved outcomes [6].

The frequency with which these activities are performed differs by race [4], with the poorest self-management and clinical outcomes being reported in African Americans [4, 5]. Because hypertension is a lifelong disease that requires self-management, there is a need to better understand the hypertension self-management strategies employed by African American older adults to improve blood pressure control [7, 8].

Studies of hypertension self-management, however, frequently do not account for the full range of contextual factors that influence African American older adults' decisions to engage in self-management behaviors. For example, African Americans who perceive stress as the cause of their hypertension are less likely to engage in self-management behaviors [9]. In addition, interventions designed on behalf of these older adults do not take into consideration personal preferences. Increasing attention is being focused on how to design an appealing and effectively tailored program

for African American older adults with hypertension. Yet, little is known about the needs and preferences of African American older adults who could benefit from hypertension self-management. This insight is critical to designing and testing patient-centered interventions that are feasible and acceptable to African American older adults.

An innovative approach to gaining critical insights into designing patient-centered interventions is cocreation. *Cocreation* is a collaborative approach to engaging stakeholders in solving complex problems. Unlike community-based participatory research, cocreation can be used with smaller groups in situations when involving an entire community may not be feasible [10, 11]. In cocreation, a stakeholder is defined as an individual that can contribute to resolution of a problem and benefit from the new solution. [11]. The stakeholders are invited to collaborate with others, asked to identify the problem, and work toward an acceptable solution. Cocreation as a methodology comes from the business management literature and has been recently used in health services research to connect those in academia with clinicians, patients, and other consumers [10, 11]. Advantages of cocreation include that it engages stakeholders early and in a “real-world setting,” which has the potential of increasing dissemination [11]. Successful cocreation includes creativity and shared governance with stakeholders in developing an intervention [10].

As an example, pharmacists used cocreation between physicians and patients to reduce inappropriate polypharmacy in the primary care setting [12]. *Deprescribing*, the process of stopping medications where the risks outweigh the benefits, was the focus of the cocreated intervention. The researchers identified providers as primary stakeholders and cocreation partners. Anderson et al. [12] conducted a literature review and held focus groups with 20 general practitioners to create a deprescribing program. The general practitioners wanted to have interactive training workshops, as mechanism for identifying at-risk patients. The workshops also allowed the option of referring the patient to an expert. After integrating the literature and focus group feedback, the researchers worked with a general practitioners and a computer programmer to design a software query. The query was designed to be used with the existing electronic medical record software [12]. The intervention cocreated by the researchers and general practitioners was designed to be practical and protocol-driven, to ease the burden of use during the patient encounter. The outcomes they expected to improve were a reduction of unnecessary medications and increased patient and general practitioner satisfaction.

Based on the previous evidence supporting cocreation, we decided to cocreate a hypertension self-management intervention with community-dwelling African American older adults. The purpose of this paper is to describe the process of cocreation to develop a hypertension self-management intervention in our sample.

2. Materials and Methods

We used the cocreation approach to conduct focus groups to develop an intervention for hypertension self-management

with African American older adults. In our study, the older adult is the stakeholder who engages in self-management of health. The focus group design was used to gather participants’ perspectives on engaging in self-management activities such as sleep hygiene, exercise, diet, meditation, prayer, smartphones, healthy self-management behaviors, and other participant-generated stress reduction activities. The focus group study was approved by the University Hospitals of Cleveland Institutional Review Board.

2.1. Participants. A sample of community-dwelling African American adults aged 60 and older with a self-reported diagnosis of hypertension were recruited. Potential participants were assessed from the general community and using an established research participant registry maintained by the principal investigator (PI) from previous research conducted in the community. Participants were screened by phone to ensure that enrollment criteria were met. Inclusion criteria were as follows: (1) self-identified as African American, (2) a diagnosis of hypertension, and (3) a reported age of 60 years or older. Exclusion criteria were as follows: (1) non-English speaking or (2) a diagnosis of severe cognitive impairment. Based on their availability to attend the focus group sessions, participants self-selected into two groups (a Wednesday group and a Saturday group). Each of the groups met twice for session that lasted two hours.

2.2. Materials. A demographic data sheet was developed for age, gender, and race. A digital voice recorder and paper for writing field notes were used for the focus group sessions. A graphic recorder was present during one of the focus groups and systematically graphed (using pictures and words) the thoughts expressed by the participants. REDCap data management and survey program was used to store the data on a secure server.

2.3. Procedure. The focus group and the cocreated intervention sessions were held in a private meeting room at a local older adult community center. Additional details related to the convenience and comfort of participants (e.g., free parking and venue near participants’ homes) were used in selecting the location for the focus groups and subsequent participant cocreated intervention. To mitigate issues related to transportation, bus passes (\$5.00 each), taxi cabs (average cost \$30.00 round trip), or gas cards (\$5.00 each) were provided to each participant to defray the cost of travel. The participants were surveyed as to the best dates and times to meet. The schedule was created and adapted so that the maximum number of participants could attend.

At the beginning of each session, the PI made introductory comments and asked each participant to speak one at a time without the use of personal identifiers to maintain privacy. Three graduate student-nurse research assistants (two African American women and one Native American man) were present to assist with notetaking and facilitation of the discussion. Participants were reminded at the beginning of each meeting, as indicated in the consent form, that the session would be audio-recorded. Cocreated ground rules were initially established and maintained for each session.

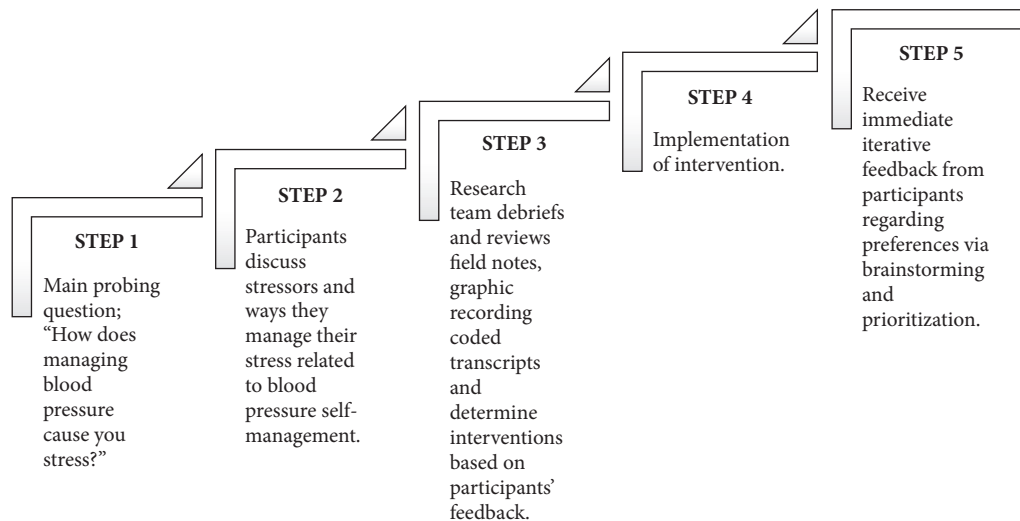


FIGURE 1: Steps to develop the cocreated intervention from focus group sessions.

The session began with focus group questions to elicit their preferences for hypertension self-management.

To determine the types of activities participants might want and suggestions for adaptation, the PI demonstrated proposed activities. The PI demonstrated a 15-minute mindfulness exercise, a strategy to reduce stress and promote relaxation [13]. Participants then completed the mindfulness exercise while in a seated position. In addition, a single content component of a kindness-based meditation was demonstrated, delivered by using the free Stop, Breathe & Think™ application. Finally, we discussed the Dietary Approaches to Stop Hypertension (DASH) diet [14], commonly recommended to people with hypertension, and each participant was provided a copy of the diet [15]. Participants were free to opt out of any of the activities. We elicited feedback on each of the activities to develop the cocreated intervention.

Investigators collected field notes during the focus group sessions in addition to audio recordings. Debriefings were held after each focus group session among with principal investigator and research assistants to review field notes to identify the preferred content for an intervention. During the debriefing session, we listed out the common themes that arose from our field notes and direct observation. Using an iterative process and member fact checking [16], the content of the intervention was verified. In the follow-up session with participants, we used fact checking to test the components of the intervention. We used brainstorming with the participants to prioritize the list of preferred interventions.

Participants returned 14–21 days later for a second focus group. The PI provided a sample presentation of the cocreated intervention based on the feedback and preferences from the previous focus group sessions. Brainstorming was used to design the content of the cocreated intervention [17]. The top 3–5 recommendations from the group were included in the intervention design. A detailed report of the content analysis that led to the intervention development that included three rounds of coding is under review in [17]. Figure 1 illustrates

an example of the decision process that was used to provide content for the intervention.

At the end of each focus group, participants received an honorarium in the form of a \$50 gift card. Participants that participated in both groups received a total of \$100. If a participant was unable to attend the second focus group session, we offered a one-on-one appointment with a research staff member, to ensure that their preferences for the intervention content would be included in the cocreated intervention.

2.4. Analytical Approach. Data analysis began after data were collected from the first focus group. The research team met between focus groups to begin designing a prototype of the intervention that was reviewed with participants at each focus group session (two cohorts met twice each). Data processing focused on identifying salient themes that informed the subsequent focus groups. Each transcript was checked for accuracy against the audio recordings. All transcribed data were deidentified, and audio files were destroyed once the transcripts were verified. A beginning list of themes was reviewed and verified by participants during each focus group session, which led the discussion for the cocreated intervention. This manuscript presents information on the design process used for the cocreated intervention. The results from the qualitative analyses are presented in a separate paper [17].

Investigator generated satisfaction surveys adapted from Bowen et al. [18] were distributed to gather data regarding overall satisfaction with the intervention, intent to use the intervention in the future, appropriateness of the intervention, and cultural relevance. The questions were on a visual analog scale with responses ranging from 1 (very poor) to 10 (excellent).

3. Results

Table 1 displays the demographic characteristics of the sample. Of the 49 African American older adults that were

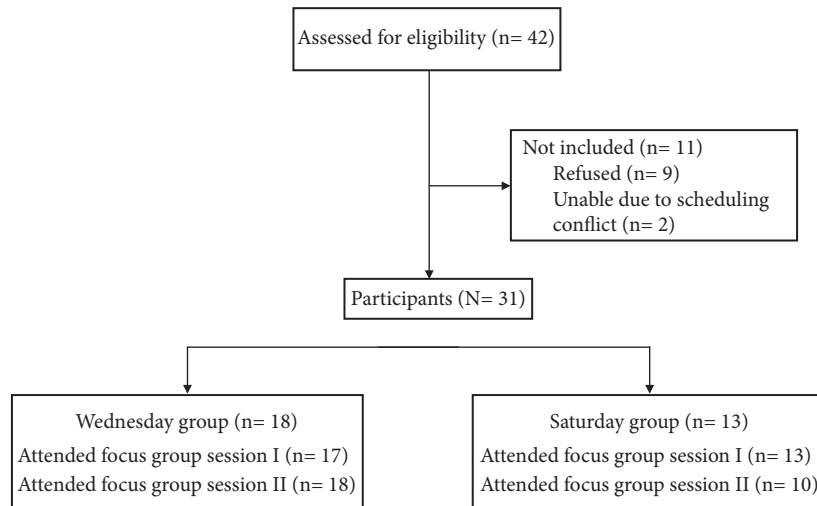


FIGURE 2: Recruitment, enrollment, and participation in focus group sessions.

TABLE 1: Demographic characteristics of community dwelling older adults with hypertension.

Variable participants (N = 31)	n	Percentage
Gender		
Female	27	87%
Male	4	13%
Age (years)		
60–69	13	42%
70–79	12	39%
80–89	5	16%
90–99	1	3%
Ethnicity		
Not Hispanic or Latino	23	74%
Hispanic or Latino	8	26%
Race		
White/Caucasian	0	0%
Black/African-American	31	100%

screened by phone, 31 were enrolled and 87% were women ($n = 27$). Figure 2 lists the number of participants who were screened, enrolled, and attended the Saturday or Wednesday session. Eighteen participants were assigned to Focus Group 1 (Wednesday group) and thirteen belonged to Focus Group 2 (Saturday group). Thirty participants participated in Session I and 28 participated in Session II. The Saturday group and the Wednesday group met two times and had an average attendance of 15 participants. One participant attended both Saturday and Wednesday. One participant switched after the first Saturday session to the Wednesday group due to work conflict.

Mode of Delivery of the Cocreated Intervention. The participants unanimously agreed that they wanted a group delivered intervention as opposed to an one-on-one intervention. The participants guided intervention delivery by deciding on the

topics to be covered, number of sessions, type of experts they wanted to deliver the education session (e.g., requested a dietitian), how long the sessions should last (2 hours), and number of sessions that they wanted. They also selected the time of day and venue for delivery of the interventions. They told us the type of homework that they wanted to do between sessions (e.g., completing a sleep diary and food diary and logging their blood pressure at home). Participants did not want the presenter of the sessions to dominate the conversation. They wanted time for suggestions and answers. They wanted time also to provide peer support to each other in the form of recipe exchanges and cooking appliance recommendations (e.g., one person recommended using the participant compensation to purchase a vegetable steamer).

Prioritized Topics for the Cocreated Intervention. The primary stressors identified by the group that influenced their blood pressure self-management were as follows: (a) measuring their blood pressure and using home blood pressure monitors; (b) difficulty communicating with family and friends; (c) organizing sleep management and pain at night; and (d) determining ways to engage in healthy eating. Based on participants' feedback, we created four biweekly (2-hour) group sessions that incorporated their suggestions and concerns. One health provider (either a registered nurse or licensed dietitian) led each session. Exercise as a way to self-manage hypertension was not brought up by participants in the focus groups.

At the request of the focus group members who helped to cocreate the intervention, the researchers successfully sought permission from the IRB to retain the participants in order for them to "try out" the cocreated intervention. An addendum to the original protocol and consent form were approved by the University Hospitals of Cleveland IRB. The series was titled "Team Learning to Take Control (TLC)," and the individual sessions were named "TLC-Monitoring Your Blood Pressure," "TLC-Communication," "TLC-Sleep and Pain," and "TLC-Healthy Eating and Learning Portions (HELP)."

Satisfaction with the Cocreated Intervention. In order to assess the participants' satisfaction with the cocreated intervention, we asked each participant to complete a four-item survey. Twenty-six surveys were completed and five were missing at random. Concerning satisfaction with the intervention, 100% responded with a score of eight or higher. Ninety-nine percent stated they would continue using what they learned from the intervention. The appropriateness of the intervention was rated 8–10 by ($n = 24$, 92.3%) and rated 6 by ($n = 2$, 7.7%) of the respondents. The cultural relevance of the intervention was rated 8–10 ($n = 22$, 84.6%) and rated 7 by ($n = 4$, 15.4%) of the respondents.

4. Discussion

This purpose of this paper was to describe the process of cocreating an intervention for hypertension self-management. Using cocreation in our study between the nurse researcher and the older adult allowed the participant (rather than the academic) to drive the design of the intervention. Participants guided intervention content by telling us what they wanted kept or removed. Participants shared their concerns around communicating with family, understanding blood pressure, and coping with the challenges of following a healthy diet. The majority of participants in the study highly rated the intervention. This may be due to their investment in the design of the intervention.

The use of a cocreated hypertension self-management intervention with a group of community-dwelling African American older adults is novel. The literature is scant on the development, use, and effectiveness of cocreated interventions. Previous studies have shown that cocreation has been effective in developing interventions [12]. The benefits of bringing together a group of individuals who share some commonalities toward a common goal are not novel [10, 11]. Using the cocreation technique in health education has the potential to have far-reaching benefits to populations at high risk of facing chronic or even co- or multimorbidities.

Although there are inconsistencies about the effects of ethnicity and gender on research participation, the group and researcher ethnic background can potentially influence participation in the focus groups [19]. Having facilitators and interventionists of a similar ethnic background may have led participants to feel more comfortable about disclosing information. We did not collect any additional data that could have led support to this assumption.

A commonly recommended intervention by nurses to patients with hypertension is exercise. However, the participants did not mention exercise as a way to self-manage hypertension. Although it was discussed in brief in the intervention delivery as appropriate, we did not push the idea of adopting an exercise routine nor make it the sole focus of an intervention session because that would have taken the power and control away from the participants.

The cocreation method is not without its challenges. One major benefit and challenge to cocreation is shared governance over the process. Interference with this process could lead to misguided results. This allowed us to demonstrate how the community-based participatory tenet

of trust building over time may work in this sample of older adults with hypertension from conception of the cocreated idea to implementation. Accommodations are often needed to promote participation. For example, in a polypharmacy study, the researchers indicated that it was difficult to schedule meeting times due to the busy nature of the clinic environment [12]. This was not a challenge for our study because our participants were mostly retired or had part-time jobs. They did, however, have transportation challenges and care responsibilities for grandchildren that we took into consideration to schedule meetings. There were a couple of occasions where a participant who was a grandparent needed to bring a grandchild to a focus group meeting. As a group, the members were willing to be flexible.

While our study provides insight into working with community-dwelling African American older adults with hypertension, additional studies are needed to examine cocreated interventions in diverse samples and across chronic illnesses. Cocreated interventions allow further examination of specific self-management strategies and specific skill sets of patients. The next steps of the cocreated intervention will include (1) analyzing our data to determine what the participants found most useful and (2) using assistive technology to manage medication routines.

5. Limitations

Due to the positive responses to participation in the focus groups, each group was larger in size than typically recommended. This may have further reduced the likelihood that individuals who are already less likely to speak up in a group setting to do so. Additionally, the male to female ratio in the groups may have reduced the likelihood of the male perspective being included in the discussion. In a mixed gender sample, there could be less to bring up sexually related topics. As a universal limitation of focus groups, the generalizability of results is limited.

6. Implications for Nursing Practice

Nurses lead development of educational interventions. Cocreation helps reduce the power imbalance in research settings. Cocreation helps establish the nurse researcher and participant as equal partners [20]. The methodology used in this study to promote health education can be incorporated into around other common topics to promote health education in a nonthreatening setting with the use of peer support. Cocreation can be applied in community-based settings, such as faith-based and civic organizations. There are potential benefits to transforming this process into other homogenous groups (i.e., other disease states or age groups).

Changes will be made to the cocreated intervention based upon the feedback of the participants such as increasing the number of sessions from four to six and providing more examples of healthy ethnic recipes. Because of the age of the focus group participants in this study, there is a potential for changes made to their self-management practices to influence their social support system across the lifespan. If the participants were caring for their grandkids, they would be

able to lead by example through grocery shopping practices and cooking habits. Future adaptations might include a family component and a group for men.

7. Conclusions

We present our experience cocreating an intervention through focus groups. Other researchers can use cocreation techniques to develop interventions. The benefits of interventions developed in this manner may be heightened by virtue of addressing what the participants indicate would most help them.

Data Availability

The data are housed at Case Western Reserve University, Frances Payne Bolton School of Nursing. Readers interested in obtaining secure access to deidentified data will need to contact Carolyn Still, Ph.D., RN (coinvestigator), at Carolyn.Still@case.edu, Case Western Reserve University, 10900 21 Euclid Avenue, Cleveland, OH 44106-4904.

Disclosure

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Acknowledgments

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Research Article

Blood Pressure and Its Association with Gender, Body Mass Index, Smoking, and Family History among University Students

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Hypertension is one of the major risk factors associated with cardiovascular diseases. In this study, we will assess the frequency of hypertension among healthy university students and its association with gender, body mass index, smoking, and family history of both hypertension and cardiovascular diseases. We screened healthy university students ranging from 18 to 26 years of age. For each participant, we performed blood pressure measurements using a previously validated device and obtained demographic data, body mass index (BMI), smoking status, and family history of both hypertension and cardiovascular diseases. Out of the total number of 505 participants included in this study, 35.2% have blood pressure between 130/80 and 139/89, and 13.5% have blood pressure of more than 140/90. We found significant gender differences in both systolic pressure ($p = 0.003$) with mean difference = 18.08 mmHg (CI: 16.13 to 19.9) and diastolic pressure ($p = 0.011$) with mean difference = 3.6 mmHg (CI: 2.06 to 5.14), higher in males than in females. Upon comparing the mean difference in both systolic and diastolic blood pressure with BMI, we found significant differences in both systolic ($p < 0.001$) and diastolic ($p = 0.002$) blood pressure. We also found that smokers have significantly ($p = 0.025$) higher systolic blood pressure (mean difference = 4.2 mmHg, CI: 3.2 mmHg to 8.8 mmHg), but no significant difference for diastolic blood pressure ($p = 0.386$), compared to nonsmokers. First-degree family history of both hypertension and cardiovascular diseases affected systolic but not diastolic blood pressure. Taking into account the adverse short- and long-term effect of hypertension, we recommend adopting an awareness program highlighting the importance of screening blood pressure in young adolescent populations, keeping in mind that both high BMI and smoking are important modifiable factors.

1. Introduction

The Middle East is known to have a significantly higher percentage of younger populations compared to the west, with the prevalence of disabling cardiovascular diseases in those younger populations significantly higher compared to western populations [1]. Moreover, the healthier the younger populations, the higher the educational achievement and the more productive they are for their developing societies [2]. A previous study showed that, in developing countries, younger populations are poorly screened for diseases, especially those associated with long-term outcomes [3].

Hypertension is one of the major risk factors associated with cardiovascular diseases, and it is also a component of

the metabolic syndrome [4]. Recently, the American Heart Association and the American College of Cardiology issued new guidelines to diagnose hypertension [5]. In these guidelines, they lowered the limit to diagnose stage 1 hypertension from 140 mmHg systolic and 90 mmHg diastolic to 130 mmHg systolic and 80 mmHg diastolic. Lowering the limit for hypertension diagnosis will increase the number of adolescents diagnosed as hypertensive. A recent study in the Philippines found a frequency of hypertension around 2.4% among university students (i.e., blood pressure > 140/90 mmHg), and 13.9% were considered prehypertensive (i.e., blood pressure > 130/80 mmHg) [6], but according to the new guidelines mentioned above, both groups are now considered hypertensive. In this study, we included healthy

university students from healthcare faculties looking for the frequency of hypertension and the effects of gender, BMI, smoking, and family history of both hypertension and cardiovascular diseases.

2. Materials and Methods

This study was approved by our ethical committee and was conducted in concordance with the Declaration of Helsinki's latest report.

2.1. Participants. We recruited university students studying at the University of Jordan in healthcare faculties, including faculty of medicine, pharmacy, and nursing. We only included healthy students (i.e., for the purposes of this study, those not previously diagnosed with hypertension). Each participant involved in this study had a previous detailed checkup upon admission to the university; the checkup included a complete history and physical examination, in addition to complete blood count and urine analysis. We recruited participants via an announcement published in relevant social media websites. Each eligible participant was instructed not to take any stimulant before blood pressure measurement (e.g., coffee and tea) for at least one hour. We measured each participant's height, weight, and both systolic and diastolic blood pressure at the nephrology clinics. Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared (kg/m^2).

2.2. Blood Pressure Measurement. We used an upper arm automated blood pressure device (an Omron 705IT (HEM-759-E)) for blood pressure measurement, a validated blood pressure device [7]. Three of the authors (A.A., D.A., and L.F.) were previously trained on blood pressure measurement, and they were instructed to rest the participant for 5 minutes prior to the measurement, support participant's arm, choose the correct cuff size, and place it over a bare arm. They measured blood pressure for each arm twice and recorded the mean for each arm, but we only included the higher mean reading for each participant.

2.3. Other Variables. We obtained both family history of either hypertension or cardiovascular diseases (either first degree, 2nd degree, or beyond) and smoking history (measured in pack-year).

2.4. Statistical Analysis. We used SPSS version 21.0 (Chicago, USA). We described our included sample using frequency (% proportion) for gender and mean (\pm standard deviation) for weight, height, systolic pressure, diastolic pressure, and BMI. We categorized BMI into the following groups: 18.5–24.9, 25–29.9, and 30–34.9, as shown in Table 4. We also categorized both systolic and diastolic blood pressure into the groups shown in Table 2. Due to the small number of participants in each group, we transformed smoking status into either a smoker (regardless of pack-year) or a nonsmoker.

We used Chi-square test followed by *Z*-test for proportions to analyze the relation between hypertension status

(nonhypertensive, stage 1 hypertension, and stage 2 hypertension) and both gender and BMI category. We used independent sample *t*-test to analyze the mean difference in both systolic and diastolic blood pressure between each gender and between smoking statuses. We used one-way ANOVA to analyze the mean differences in both systolic and diastolic blood pressure for BMI and family history of both hypertension and cardiovascular diseases. We reported our data using mean difference and 95% confidence interval (CI), and we used a *p* value threshold of 0.05.

3. Results

A total of 505 participants were included in this study with a mean age of 21.2 years (± 1.4 , ranging from 18 to 26 years). They were 188 (37.2%) men and 317 (62.8%) women. Mean, standard deviation, minimum, and maximum for the included sample's weight, height, systolic BP, diastolic BP, and BMI are shown in Table 1. Out of the total 505 participants, the percentages of underweight, normal, overweight, and obese were 8.7%, 66.1%, 21.4%, and 3.8%, respectively.

For smoking, only 111 (22%) participants were smokers with a mean of 1.04 pack-years (± 2.08). Family history of hypertension is present in 126 (25%), as 77 (15.3%) have a first-degree history and 49 (9.7%) have a second-degree family history of hypertension. Family history of cardiovascular diseases is present in 46 (9.1%), as 15 (3%) have a first-degree history and 31 (6.1%) have a second-degree family history of cardiovascular diseases.

Detailed frequencies for each hypertensive category are shown in Table 2. For systolic blood pressure, we found that 90 (17.8%) participants have blood pressure equal to or more than 130 mmHg, and 31 (6.1%) participants have blood pressure equal to or more than 140 mmHg. For diastolic blood pressure, we found that 229 (45.4%) participants have blood pressure equal to or more than 80 mmHg, and 53 (10.5%) participants have diastolic blood pressure equal to or more than 90 mmHg.

We found significant gender difference ($p < 0.001$) regarding hypertension, as 25.1% of males do not have hypertension ($< 130/80$) compared to 74.9% of females. Moreover, we found significant difference ($p < 0.001$) between each BMI category and hypertension status. Details regarding both gender differences and the difference in each BMI category with hypertension status are found in Table 3.

We found significant gender differences in both systolic BP ($p = 0.003$) with mean difference = 18.08 mmHg (CI: 16.13 to 19.9) and diastolic BP ($p = 0.011$) with mean difference = 3.6 mmHg (CI: 2.06 to 5.14). Upon comparing the mean differences in both systolic and diastolic blood pressure with BMI, we found significant differences in both systolic ($p < 0.001$) and diastolic ($p = 0.002$) blood pressure. Details regarding these differences are shown in Table 4. For smoking status, we found that smokers have significantly ($p = 0.025$) high systolic blood pressure (mean difference = 4.2 mmHg, CI: 3.2 mmHg to 8.8 mmHg), but no significant difference for diastolic blood pressure ($p = 0.386$). Upon comparing the mean differences in both systolic and diastolic blood pressure among participants with (first or second degree)

TABLE 1: Mean, standard deviation, minimum, and maximum for the included sample's measurements.

	N	Minimum	Maximum	Median	Mean	Std. Deviation
Weight (Kg)	505	41	128	63	65.52	14.39
Height (m)	505	1.46	1.97	1.61	1.68	0.092
Systolic (mmHg)	505	83	159	115	116.71	13.58
Diastolic (mmHg)	505	42	103	79	78.80	8.69
BMI (Kg/m ²)	505	15.04	36.09	22.67	23.0	3.55
Smoking (Packs/year)	505	0	11	0	1.04	2.08

TABLE 2: Detailed frequencies for each hypertensive category.

blood pressure	New hypertension limit	Old hypertension limit	Frequency (%)
<130/80	Not hypertensive	Not hypertensive	259 (51.3%)
130–139/80–89	Stage 1 hypertension	Pre-hypertensive	35.2 (35.2%)
>=140/90	Stage 2 hypertension	Stage 1 hypertension	68 (13.5%)

TABLE 3: Details regarding both gender differences and the difference in each BMI category with hypertension status.

	Gender		BMI category			
	Male (%)	Female (%)	<18.5	18.5–24.9	25–29.9	30–34.9
Hypertension Status						
Non-Hypertensive	65 25.1%	194 74.9%	30 11.6%	184 71.0%	44 17.0%	1 0.4%
Stage 1 hypertension	74 41.6%	104 58.4%	14 7.9%	109 61.2%	44 24.7%	11 6.2%
Stage 2 hypertension	49 72.1%	19 27.9%	1 1.5%	42 61.8%	20 29.4%	5 7.4%

TABLE 4: Differences in mean systolic and diastolic blood pressure between normal BMI (reference) and other BMI categories. The “p value” indicates the significant level of the mean difference, as significant levels with p values < 0.05 are annotated with *.

Blood pressure	Reference BMI (18.5–24.9)	Other BMI	Mean difference between reference and other BMI	p value	95% Confidence Interval	
					Lower Bound	Upper Bound
Systolic	18.5–24.9	<18.5	6.811*	.004	1.63	11.99
		25–29.9	–8.494*	.000	–12.07	–4.92
		30–34.9	–17.978*	.000	–25.60	–10.36
Diastolic	18.5–24.9	<18.5	2.240	.364	–1.31	5.79
		25–29.9	–2.073	.130	–4.52	.38
		30–34.9	–5.226*	.050	–10.44	–.01

and without family history of hypertension, we only observed significant difference in mean systolic blood pressure (but not diastolic) in participants with first-degree family history of hypertension (but not in second degree), as systolic blood pressure for those with first-degree family history compared to those without is higher by a mean of 4.4 mmHg (CI: 0.4 mmHg to 8.3 mmHg). Family history of cardiovascular diseases has a similar effect as found in hypertension, as a difference in blood pressure is only found in systolic blood pressure upon comparing participants with first-degree history of cardiovascular diseases and those without (mean difference of 6.7 mmHg higher in those with a family history, CI: 1.6 mmHg to 15.1 mmHg).

4. Discussion

In this study, we found that if we were to apply the most recent threshold for the diagnosis of hypertension [5], 17.8% of our university students will be diagnosed with systolic hypertension (i.e., blood pressure > 130 mmHg) compared to 6.1% using the previous guidelines (i.e., blood pressure > 140 mmHg), and 45.4% of the students will be diagnosed with diastolic hypertension (i.e., blood pressure > 80 mmHg), compared to 10.5% using the previous guidelines (i.e., blood pressure > 90 mmHg). Moreover, we found significant gender differences in both systolic blood pressure with mean difference = 18.08 mmHg and diastolic blood pressure with mean difference = 3.6 mmHg, higher in males than in females.

BMI was also a major contributor to the high blood pressure in our university students, as the mean difference in systolic blood pressure between participants with BMI < 18.5 and 30–34.5 was 24.8 mmHg, and the mean difference in diastolic blood pressure between participants with BMI < 18.5 and 30–34.5 was 7.5 mmHg.

Previous studies showed that adolescents are not usually exposed to situations that require blood pressure measurements [3], despite the fact that several reports, including the present study, show that adolescents have relatively high rates of blood pressure, especially with the lower limits adopted recently for hypertension diagnosis [5], which were found mostly during studies [8]. Early detection of high blood pressure is usually difficult in adolescents, mostly due to underestimation for the long-term effect of high blood pressure and BMI and the relatively minor effect of these diseases on the well-being of adolescents compared to adults [9].

Generally, overweight and obese adolescents have more body fat and higher blood pressure than normal weight adolescents [8], and a strong relation between BMI and blood pressure is well established for both systolic and diastolic blood pressure [10]. This relation is also present for our population, with stronger effect of BMI on systolic blood pressure. Previous studies found high prevalence rates of cardiovascular risk factors, including components of metabolic syndrome, in undergraduate university students, with frequencies reaching 60% [11]. The high prevalence of metabolic syndrome components and the strong relation between BMI and blood pressure should direct awareness for the importance of lowering BMI, which will improve blood pressure, especially for university students.

The effect of smoking on blood pressure can be divided into an acute effect due to sympathetic nervous system stimulation and a chronic effect due to chronic cigarette smoking [12]. Acutely, smoking leads to an increase in both heart rate and blood pressure through a mechanism involving sympathetic nervous system stimulation [13]. The chronic effect of smoking is controversial; several studies found a decrease in blood pressure in chronic smokers, but these studies were either outdated [14, 15] or only involved women [16]. A larger study from a nationally representative sample showed a finding consistent with our study, which is an increase in systolic blood pressure without an effect on diastolic pressure [17]. This effect on systolic without diastolic can be explained by aortic stiffness caused by smoking [18]. Moreover, smoking was recently found to be associated with hypertensive heart disease [19].

The effect of having a family history of hypertension in the development of hypertension is already established and in concordance with this study, where having more than one member or having closer relative diagnosed increased the risk of having hypertension [20]. Previous reports showed that boys have higher blood pressure than girls significantly after the age of 16 [21]. Our results were in concordance with these reports, as male students have mean systolic blood pressure of 18.1 mmHg higher than female students and mean diastolic blood pressure of 3.6 mmHg higher than female students, keeping in mind that the minimum age for our included sample was 18 years. The higher blood pressure in

males compared to females was also found in several other populations [8, 10].

After issuing the new guidelines jointly by the American Heart Association and American College of Cardiology [5], debate increased on the low threshold of hypertension diagnosis proposed. In this study, after showing a significant gender difference in blood pressure, a difference that might reach approximately 20 mmHg in systolic blood pressure, we believe that it is time to adopt a hypertension threshold based on gender, age, and other demographic variables. Larger studies also appreciated the difference in blood pressure based on the demographic variables [22].

4.1. Study Limitations. Despite the rigorous instructions given to ensure blood pressure measurement accuracy, this study has some limitations. Including other factors that might affect blood pressure (e.g., blood tests for cholesterol) will further clarify the relation between blood pressure and BMI. Future studies should investigate the long-term effects of having high blood pressure early during adolescent life.

5. Conclusion

We conclude with the existence of a high frequency of high blood pressure among university students, especially if we adopt the new limits for hypertension diagnosis. We also found a significant association between BMI and smoking with blood pressure, both of which are associated with higher blood pressure (only higher systolic BP for smokers), and both can be modified. Moreover, gender differences also should be considered, as boys have higher mean blood pressure compared to girls. Finally, having first-degree family history of hypertension or cardiovascular diseases has been shown to be associated with higher systolic blood pressure.

Data Availability

Data are available upon request.

Conflicts of Interest

All authors declare no conflicts of interest.

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Research Article

Factors Influencing Compliance and Health Seeking Behaviour for Hypertension in Mukono and Buikwe in Uganda: A Qualitative Study

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Background and Methods. Hypertension is a global public health challenge and a leading risk factor for cardiovascular morbidity and mortality. Hypertension control rates are low worldwide, and delay in seeking care is associated with increased mortality. **Methods.** In a qualitative study, known hypertensive patients were interviewed to explore factors influencing compliance and health seeking behaviour (HSB). Data was analyzed following a semantic thematic analysis approach. **Results.** Patients sought various channels of care for their hypertension. Self-medication and access to antihypertensive drugs with or without prescription were common as well as use of herbal remedies. Regular monitoring of blood pressure was not a common practice. Factors influencing HSB were related to health systems and the patient socioeconomic and structural environment. The main system issues were related to availability and attitudes of staff and shortage of supplies and medicines. The patient factors were related to awareness, perceived severity, perceived effectiveness of therapy, adverse effects, and perceived fears of lifelong dependence on medicines. The patient socioeconomic status played a role as did the marketing of traditional medicine. **Conclusion.** Patients seek varied channels of care for their hypertension. Strategies to address the multifactorial dimensions that affect HSB are needed to improve hypertension control in this population.

1. Introduction

Hypertension is a leading risk factor for cardiovascular morbidity and mortality worldwide [1]. A comparative risk analysis of the burden of disease and injury associated with 67 risk factors revealed that hypertension (also known as high blood pressure) is the leading risk factor for mortality with 7% of deaths attributable to it [1]. It is predicted that, by 2025, the number of adults with hypertension will increase by about 60% to a total of 1.56 billion and most of the cases will occur in low and middle income countries (LMIC) [2]. Urbanization and the epidemiological transition characterised by an aging population, physical inactivity, obesity, increasing alcohol consumption, and high salt intake are contributing to the increasing rates of hypertension in

LMIC [3]. Hypertension is a “silent killer” [4] and data suggests that hypertensive heart disease could be the most common form of cardiovascular disease (CVD) in Africa [5]. Unfortunately, most cases of hypertension are asymptomatic and as a result, hypertensive patients often seek medical attention late or when they have developed complications such as strokes, heart attacks, heart failure, and kidney failure [3]. In their publication, Cruickshank et al. on the rule of halves reported that 50% of the hypertensives are known, of the known hypertensives, half are on treatment and of those on treatment, half are controlled [5]. The World Health Organization (WHO) projected that, over the next ten years, Africa will experience the largest increase in death rates from CVDs. Consequently, the negative economic impact of CVDs will be felt more on the African continent [6] and the cost of

handling chronic illness will lead many households to poverty [7].

Health seeking behaviour (HSB) has been defined as any activity undertaken by individuals who perceive themselves to have a health problem or to be ill for the purpose of finding an appropriate remedy. The desired HSB is responding to an illness by seeking help from a trained allopathic doctor in a recognized health care center [8]. It is well established that HSB is influenced by manifestation of symptoms [9, 10]. However, many hypertensive individuals may not be aware and may not have any symptoms to compel them to seek care. Even among those presenting with symptoms and those who are aware hypertensive, their HSB is suboptimal [11, 12]. Hypertension control remains very low [13] and attributable reasons revolve around noncompliance due to side effects of the medication, lack of information and support, difficulty obtaining the medication, poverty, low education, and poor access to health care [14–16]. In addition, health system deficiencies such as lack of antihypertensive medication, the physicians' inertia in treating hypertension, and long distance to the health facilities have been implicated in affecting HSBs and control of hypertension [13, 17, 18]. Delays in seeking care for hypertension are associated with increased mortality [19] and the benefits of early treatment and control are also well established [20–22].

Like most of Sub-Saharan Africa, Uganda's health care system was established with a greater orientation towards communicable diseases. It is only in the past 15 years that the NCD agenda started featuring in the national health strategic plan of the Ministry of Health [23]. The current health service delivery system has a number of gaps ranging from lack of preventive services for NCDs to lack of essential supplies for managing NCDs [24].

Over the last 20 years, Uganda has witnessed an increasingly aging population which has ushered in increasing rates of lifestyle-related chronic noncommunicable diseases [25]. Notably, increasing cases of obesity, diabetes mellitus, and hypertension, along with such complications as stroke, and heart diseases are reported [25]. Data from the Health management information system (HMIS) suggests that hypertension is the most reported NCD and community surveys also suggest that one in five of every adult ≥ 18 years have uncontrolled hypertension [26]. The detailed reasons for low levels of hypertension control and inadequate HSB in this setting are not well understood.

We explored compliance and HSBs for hypertension using qualitative approach in order to understand reasons for low levels of hypertension control. Understanding the HSB for hypertension is vitally important in designing programs for hypertension control and enhancing quality standards in healthcare delivery [8].

2. Methods

2.1. Setting and Design. From August to October 2014, we conducted a community descriptive qualitative study and performed semistructured individual interviews with 48 patients with known hypertension in Mukono and Buikwe districts in Uganda. According to the Uganda population

and housing census area specific profiles, 78% and 72% of the population in Buikwe and Mukono, respectively, live in rural areas [27]. The Uganda National Health System is made up of the Public and the Private sectors. Uganda implements a level based healthcare delivery system with a referral framework from a lower facility (Health Center (HC) II, III, IV) through hospitals at the district, regional, or national level. Mukono and Buikwe districts combined have six (6) hospitals, 4 HCIV, 27 HCIII, and 57 HCII. Moreover, most of these facilities are ill-equipped to provide services for hypertension. For example, essential ingredients including diagnostic equipment, antihypertensive medicines, and personnel are scarce [28]. Secondly, conducting this study in this setting would provide incremental evidence to our previously conducted WHO Stepwise Approach to Chronic Disease Risk Factor Surveillance (STEPS) study [29]. In the STEPS study, we observed an unacceptably high prevalence rate of hypertension and suboptimal treatment and control [29].

2.2. Sampling. A purposive sample of patients with known hypertension was identified from the database gathered two years before [29]. The STEPS, conducted in 2012, enrolled 4653 study participants of whom 258 were hypertensive patients and aware of their hypertension. The data set for the 258 patients was organised by gender, residential status, and district to select patients for enrolment into the current study. To generate a wide range of experiences, a fairly big sample size (48) comprising of a varied group of patients (males' and females, urban and rural, Buikwe and Mukono districts) were interviewed. The final sample is comprised of equal number of patients drawn from both districts of Mukono and Buikwe, 17 males, and 24 rural residents. All participants consented except two males.

2.3. Data Collection. Data were collected by one of the lead investigators (GM) and three graduate research assistants who underwent a rigorous and extensive 5-day training to standardise data collection procedures. The training entailed a review of the study objectives, conduct of qualitative inquiries, blood pressure measurement using a validated automated digital sphygmomanometer (Omron model M3W) with an appropriate cuff size, interpersonal communication skills, ethics, confidentiality, and informed consent, seminars on one-on-one interviewing techniques, and detailed instructions on using the semistructured interview protocol. The use of semistructured interview guides (Appendix) enabled data gathering on background characteristics of the study patients, compliance, and HSBs for hypertension. Interviews were conducted at the participants' homes. Each interview lasted one hour on average after which the patients' blood pressure was measured thrice one minute apart. Measuring blood pressure after the interview allowed the patient to relax and also prevented any biased responses that would arise if measurements were done before the interviews. All interviews were audio-recorded with consent from each patient and the average of the three readings was used to estimate the patient blood pressure.

2.4. Ethics Statement. Ethical approval was granted by Makerere University School of Public Health Higher Degrees-Research and Ethics Committee and the Uganda National Council of Science and technology. Each participant provided written informed consent.

2.5. Data Management. All qualitative data were transcribed verbatim and then translated into English from the local language. Each transcript was reviewed by at least two research assistants and one of the investigators (GM) for content and completeness. Final transcripts were stored securely on passworded external drives and later exported to ATLAS.ti version 7, qualitative data management software for further management.

2.6. Data Analysis. To identify the factors influencing compliance and health seeking behaviours for hypertension, we analysed the data following a semantic approach in thematic analysis [30]. Using free coding options in ATLAS.ti, GM read each transcript and extracted relevant data to generate codes related to compliance and health seeking behaviours. The codes were reviewed to identify patterns within the data [31] and iteratively compared with the original transcripts. Following the review and with use of code families' options in ATLAS.ti, the codes were sorted into groups (to generate subthemes) and where appropriate were split or dropped or renamed if better subthemes were obtained. The subthemes were further reanalysed to generate themes and overarching themes. For quality control, and to ensure that the interpretation was close to the content and to support reflexivity, the process of analysis and output at every stage of the analysis was regularly reviewed and discussed with SA and HB.

3. Results

3.1. Participants and Context. Table 1 shows study participants' characteristics and their current blood pressure profiles as measured at the time of the interviews.

As shown in Table 1, 48 patients were interviewed between August and October 2014. Of these, 17 were males, 24 were rural residents, 35 were married, and 23 had attained post-primary education. The median age was 54 (males 54, females 51.5). Very few patients, 8, had their hypertension under control (SBP < 140 mmHg and DBP < 90 mmHg). Majority ($n = 20$) were stage one hypertensive and sizable proportions were stage 2 ($n = 11$) and stage 3 ($n = 9$) hypertensive. Self-medication and access to antihypertensive drugs with or without prescription from drug outlets were common as well as use of herbal remedies. Some patients also reported engaging in life style interventions such as cessation of alcohol consumption, increased physical activity, and dietary modifications. Regular monitoring of blood pressure was not a common practice. Modern healthcare for hypertension was sought widely from all levels of health facilities including drug shops, pharmacies, private health clinics, health centers (II, III, and IV) and hospitals. Herbal remedies in use included garlic, ginger, pumpkin leaves (*essunsa*), herbal mixtures (names unknown), African eggplant (*Katunkuma*), Moringa,

TABLE 1

Characteristics	Number
Sex	
Male	17
Female	31
Residential status	
Rural	24
Urban	24
Education status	
Primary or less	25
Post primary	23
Marital status	
Single	13
Married	35
Age	
Overall median age	54
Median age (female)	51.5
Median age (male)	54
Measured BP on the interview date	
(SBP < 140 mmHg and DBP < 90 mmHg)	8
Stage 1 (SBP = 140–159/ DBP = 90–99)	20
Stage 2 (SBP = 160–179/ DBP = 100–109)	11
Stage 3 (SBP ≥ 180/DBP ≥ 110)	9

Mumbwa, spider plant (*ejjobyo*), aloe vera (*kigaji*), dried banana leaves, neem tree, chlorophyll extracts, human urine, Tianshi (Chinese herbal), and African night shade (Nakati).

3.2. Factors Influencing Compliance and Health Seeking Behaviour for Hypertension. The 3 thematic key issues influencing HSB for hypertension were related to the health system, the patient, and the broader socioeconomic and structural environment. Consequently, we organise the key findings (themes and subthemes) under each of these three overarching thematic areas. Figure 1 illustrates the schema of the identified themes and subthemes.

3.2.1. Health System Factors. Under the overarching theme of health system factors, five themes influencing compliance and HSBs were identified: (1) availability of medicines, personnel, and diagnostic supplies; (2) high burden of acute care at health facilities; (3) traditional medicines; (4) perceived provider abilities/behaviours and overall quality of care, and (5) patient waiting times at the facilities.

(1) Availability of Medicine, Personnel, and Diagnostic Supplies

Medicines. Patients noted that availability of or the assumption of [modern] medicines was readily available at health facilities and related costs played a key role in their seeking behaviours for hypertension. In private health facilities and private pharmacies, patients reported that antihypertensive drugs were readily available. However, high costs of these medicines were a deterrent to access. As such, they echoed that only those who had the money accessed the medicines as illustrated by the following patient in a local proverb.

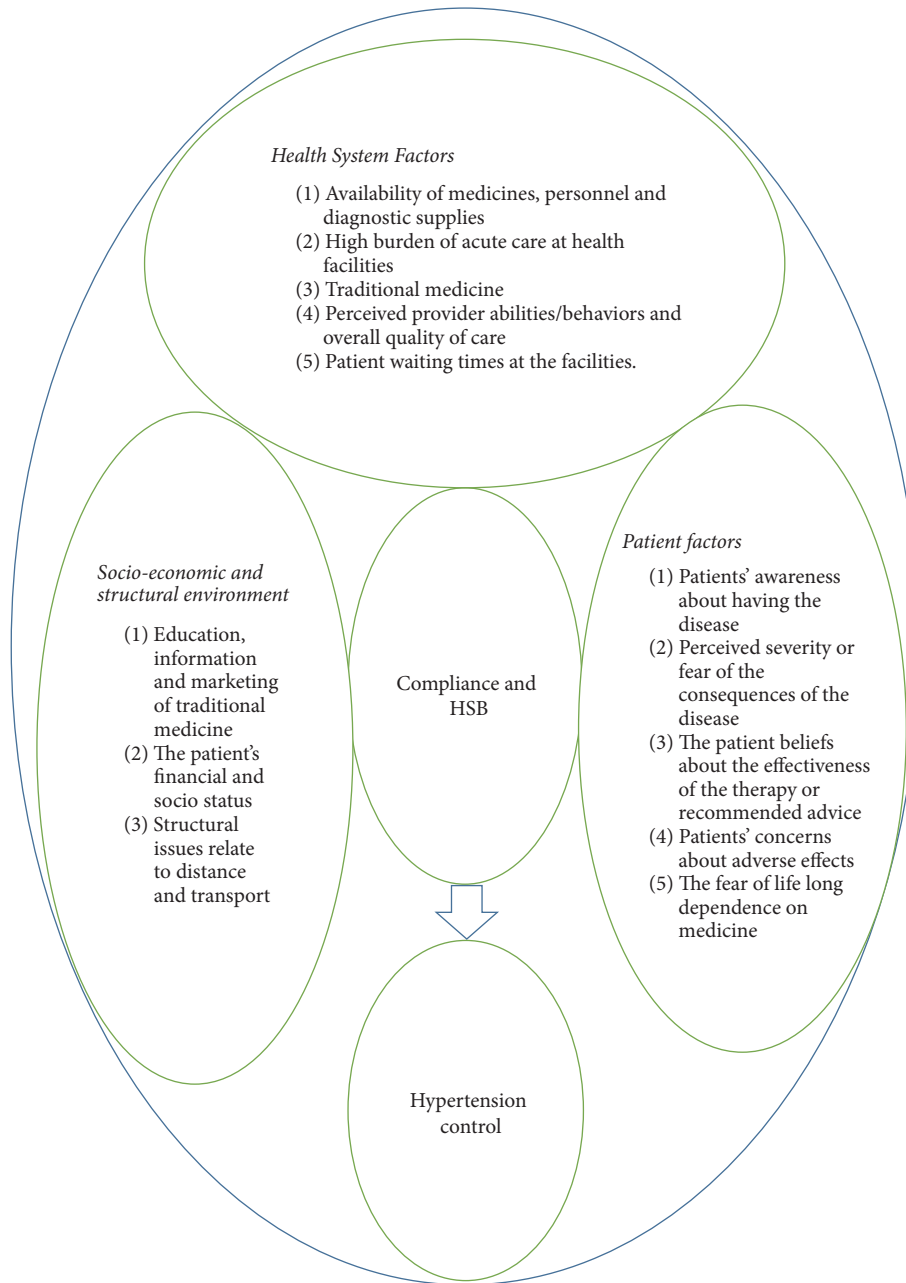


FIGURE 1: Factors influencing compliance and health seeking behaviours for hypertension among patients in Mukono and Buikwe Districts in Uganda.

When you are a poor man, you don't prick a Swahili ban [local bread] or else you get beaten if you prick and don't buy. (8 Bulamba-Bugungu_Male 1-Buikwe, Rural)

As a caveat to turn away from high costs, self-medication was commonly reported from drug outlets, which dispensed medicines with or without prescription and in any quantities depending on the patients' affordability. But even with this option, cost still deterred patients from access as illuminated by the following patient.

Apart from the medicine he gave me. I failed to buy the medicine he had prescribed; even the last

time I went to him; I failed to buy the medicine because it's expensive. One tablet costs 2,000 shs; and yet I had to swallow one per day for one month. I calculated and it was 60,000 shs; so I only swallowed the medicine he gave me; and then stopped. (19 Kanyogoga_Male 2-Buikwe, Urban)

The costs of antihypertensive medicine were offset when the health facilities provided the medicine free of charge to patients. Indeed, patients attested that finding medicines at the health facilities was a motivation for their health seeking behaviours. However, lack of medicines had a negative implication on their compliance and health seeking

behaviours. Patients expressed a sense of disappointment when they visited a health facility in anticipation of getting free medicines only to be given prescriptions to go and buy medicine elsewhere.

I went there four times; the first two times I got the medicine; while the other two times I was told that there was no medicine. So I realized that I was wasting time and stopped going there. (20 Kateete_Female1)

Another also echoed, “they gave me that medicine that I have told you [valium] and they told me to buy the other drugs since it was out of stock in the hospital. I didn’t buy it; the truth is that the medicine was expensive” (12 Geregere Majjani_Female 1-Buikwe, Urban).

Personnel. Finding a service provider at a health facility was also critical in influencing health seeking behaviour of hypertensive patients. Patients were motivated to go to a health facility where they were sure of finding health workers. Most acknowledged that the situation was improving with establishment of specialised clinics especially at the national referral hospital, which run most days of the week.

Previously I only saw a doctor once a month but now, I can see the doctor any day between Monday to Friday. (1 Anthony_Male 1)

Some, however, were still hindered by lack of providers at health facilities.

Doctors would come once in a month so I didn’t have the vigor to go to hospital for care. (16 Kabumba_female 1-Mukono, Rural)

Lack of personnel as a barrier to health seeking behaviour was mainly reported by patients from the rural areas. However, some also stressed that their district hospital operated a one-day clinic in a week for diabetes and hypertension which limited access to specialised health workers for hypertension.

Diagnostic Supplies. Supply issues entailed the availability or lack of/inadequacies in diagnostic equipment. It was common for patients in rural areas to report that they lacked a place where they could have their hypertension routinely monitored.

... the clinics here in the village do not have the BP machines ... all they do is to ask you; ‘what are you suffering from?’ Then they base on what you have told them to give you a few tablets to relieve you from the pain. (6 Bukamunye B.Female 2-Buikwe, Urban)

Another patient reported, “the biggest challenge we are facing as people with hypertension in this village is lack of somewhere we can go for emergency blood pressure monitoring” (41 Ssaza_female 3- Mukono, Urban).

(2) *High Burden of Acute Care at Health Facilities.* It was quite interesting to note that some patients did not seek care because they thought health workers would not attend to them since they [patients] did not have severe symptoms to warrant attention. This was especially in relation to those who desired regular BP monitoring. They said that hospitals were full of the severely ill meaning that a visit to health facilities for routine hypertension monitoring would be an additional burden to an already overwhelmed system. This subtheme was best illuminated by a patient (33 Malongwe Ajjija_male 2-Buikwe, Urban) who reported that it was difficult to just walk into a health facility and request a BP measurement. He said that such a daring would be considered luxurious because most of the facilities focus their efforts and resources on the very ill not the healthy looking individuals who walk in for BP measurements. The participant exemplified as follows:

One challenge has been the monitoring of blood pressure ... It’s hard to just walk up to a health worker and tell them you would like to check your blood pressure ... It’s hard for the health worker to really give you attention ... because you would have gone there for luxury and not as a patient. So when I would request for a blood pressure check-up; they would ask what the problem was. They cannot work on a person like me yet there are many patients who need help. (33 Malongwe Ajjija_male 2-Buikwe, Urban)

(3) *Traditional Medicine.* With respect to the challenges surrounding access to modern health services, some patients resorted to using alternative medicines and seeking care from traditional practitioners. Most patients seeking complimentary medicines used herbs and some reported that they consulted traditional healers for their hypertension. Patients considered herbs easily accessible and to a certain extent comparably affordable. Planting them in the back yards enhanced access to herbs. In addition, most of the herbal remedies reported were readily available on the local market. However, it was also noted that some special herbs including those exported from abroad were sometimes difficult to access and expensive and that some traditional healers asked for certain items such as chicken and goats, which deterred patients from consulting them.

At first I tried local medicine like mumbwa but when the traditional healers started asking goats from me I couldn’t manage that because I didn’t have the money to buy these goats so I stopped visiting traditional healers (47 Vvuluga_female 1-Buikwe, Urban). It was Chinese medicine; ... my brother brought it for me. I drank it ... in fact I improved slightly; the fast heart beats stopped and my head also stopped hurting; only that I failed to use it because of my finances. (14 Jagary Cable_female 1-Buikwe, Urban)

It was also observed that traditional healers do not necessarily stay in the same communities where they provide their services. In some cases, patients reported that they abandoned their local treatment remedies because their providers

[traditional healers] were out of reach. This patient alluded as follows:

From the time I would buy their medicine it would take like two to three months before they [traditional healers] returned to our village, this stopped me from using their medicine. (16 Kabumba_female 1-Buikwe, Urban)

(4) *Perceived Provider Abilities and Behaviours and Overall Quality of Care.* This theme comprises the four subthemes: (1) patients' perceptions about their providers' abilities in terms of skills and knowledge competences; (2) perceived providers' attitudes towards work and the feeling of being treated with or without respect; (3) providers' advising role towards their patients' health seeking behaviours; and (4) perceived quality of care.

Patients' Perceptions about Their Providers' Abilities in Terms of Skills and Knowledge Competences. Whereas most patients perceived their providers to have sufficient knowledge and the required skills to manage hypertension, some had reservations. Those who had reservations depicted their providers as not having sufficient competencies. They felt the providers focused on treating symptoms rather than conducting a proper disease diagnosis prior to treatment.

... it is better for the health worker to know the disease they are treating by examining the patient, but for them [referring to health workers] they just dish [give] medicine to patients based on whatever disease the patients mentions ... If you tell them [health workers]; 'I have headache due to over sleeping or that I have headache because I have fever', that is it - then he/she [health worker] will give you tablets to treat that. (6 Bukamunye B_Female 2-Buikwe, Rural)

Providers implicated with such incompetence were mainly those operating at the lower level health facilities especially drug outlets, pharmacies, and rural health facilities. On the other hand, most patients had confidence in medical doctors. They also felt that hospitals were better prepared in managing hypertension compared to private and lower health facilities.

Perceived Provider Attitudes towards Work and the Feeling of Being Treated with or without Respect. Patients noted that providers exhibited different attitudes towards their work and their patients. They felt very comfortable seeking care from providers who were friendly. Some providers were implicated in having unwelcoming behaviours and negative attitudes towards patients. Examples of negative behaviours reported in this study included barking at patients, treating patients disrespectfully, and being unconcerned. Patients noted that it was common to find such behaviours in the public facilities. Most patients complemented private health facilities for their welcoming and caring attitudes. In fact, one patient stated that, in the private clinics, they are treated as customers which motivates them to seek care from the private clinics although he was also quick to speculate that the warm care was possibly

because of the financial incentives [since patients pay for the service] and the strict leadership. Some patients also noted that they did not appreciate the decision making process that their providers followed while helping them to get appropriate remedy for their ailments. They felt that providers exhibited unnecessary delays, which resulted in negative health outcomes. One patient expressed dissatisfaction and wondered why the healthcare workers could not agree on the next course of action and refer her in a timely manner given that they were failing to diagnose and manage her condition.

Nurse ... 'her case cannot be handled here' ... 'we have to refer her to Mulago hospital; she will die here.' She would continue to tell the others to allow me go to Mulago stressing that they cannot handle me ... But there was a nurse who would prescribe medicine and tell me, 'These will work for you' so that's how I was. I would always go back to them complaining of not sleeping well; it was like that every time; until I got the doctor from Mulago. (37 Namengo Female 1- Buikwe, Urban)

Providers' Advising Role towards Their Patients. In spite of the reported challenges with some modern health care providers, patients were to a greatest extent likely to follow the advice they received from their providers. Certain patients said that they were using herbal remedies because they had been advised to do so by their healthcare providers. However, others said that they were not using herbal remedies because their healthcare providers advised them against arguing that concurrent use of herbal and modern medicine could result in contraindications and that the efficacy and effectiveness of such medicines were not established. On the other hand, some traditional practitioners were also discouraging their patients from using modern medicines arguing that they were not effective.

I left Nagalaama [hospital] with some medicine and when I reached the herbalists' place they stopped me from taking modern medicine. (17 Kabumba_female 2-Mukono, Rural)

Health care providers also advised patients on lifestyle modification. Some patients were advised on salt intake, dietary modification, physical activity, alcohol consumption, and smoking. But the patients were also keen on reporting that although they put effort in following their providers' advice, some of the advices were not contextually feasible.

... he told me not to eat many things; and yet I cannot stop eating some of those that he mentioned; he told me not to eat 'posho'; sweet potatoes ... and told me not to eat one meal; which is difficult in a village. (20 Kateete Female 1-Mukono Rural)

Perceived Quality of Care. This theme generated conflicting reports. Some respondents felt that government hospitals provided high quality services compared to private health facilities in spite of the high patient loads and the long waiting time. On the other hand, patients commended private health

providers for being swift in service provision, although they had concerns with regard to provider competencies in private facilities. Meanwhile, the majority felt that modern medicine had an edge over traditional medicine, although some respondents noted that the quality of traditional medicine is improving especially in terms of practice, dosing, and packaging.

Patient Waiting Time at the Facility. Patients noted that it was very stressful to spend the whole day at a health facility waiting to be treated. The long waiting time was attributed to (1) high patient volume vis-a-vis the limited number of health workers; (2) sluggishness and being unconcerned on the side of the healthcare workers, and (3) a lack of clear patient flow protocol that was characterised with favouritism and lack of respect.

it is because by the time you go to the hospital very early in the morning, you were feeling unwell but in the process of queuing in the hospital, there can come someone who knows the doctor and the person overtakes you – one thing that is annoying because you come to the hospital after you have slept unwell and only to be disappointed – do you see such a thing? (Njeru_Female 1 Buikwe, Rural)

As a consequence, some patients stopped going to certain hospitals because of the long time they spend trying to get a service. Moreover, they reported that they had to cue at every service point (consultation room, laboratory room, and dispensing room). They felt very high workload and long waiting times were most prominent at public health facilities.

3.2.2. Patient Related Factors. Another overarching theme influencing compliance and health seeking behaviour for hypertension was “patient related factors.” The subthemes building up this theme: (1) awareness about having the disease; (2) perceived severity or fear of the consequences of the disease; (3) beliefs about the effectiveness of the therapy; (4) concerns about adverse effects; and (5) the fear of dependency on long-term medication.

Patients’ Awareness about Having the Disease. Awareness “the state of being aware or having knowledge that one is hypertensive” played critical role in HSB. Some patients reported presenting with no symptoms at the time of diagnosis, whereas others reported mild or severe symptoms as depicted by the following patients.

When I went to the first clinic, they checked me and they said that I was hypertensive – I couldn’t believe it. I went to another clinic and they still measured my BP and they told me that I was hypertensive, I still didn’t believe it. I went to the third clinic where they measured my BP again and they found me hypertensive and they even started me on the drugs to treat it. (10 DFI_female 2-Mukono, Urban)

Another patient reported, “I did not have any symptom; I was like any other normal person. I

did not have rapid heartbeats” (14 Jagary Cable Female 1), and another one also narrated, “I really think that I had been hypertensive for quite a long time though I was unaware” (41 Ssaza_female 3-Mukono, Urban).

Respondents felt that creating awareness was dependent on having the patients’ blood pressure measurements taken at a health facility or during a community outreach. However, they noted that opportunities to have their blood pressure measurements at the facilities or outreach sites were scarce. Because of the limited opportunities, and the asymptomatic nature of hypertension, most patients got to learn about their hypertension after experiencing severe symptoms or presenting with signs of end organ damage such as stroke.

I took long to know that I was hypertensive ... One time in 2000, I was taking my agricultural produce to Kampala for sale, while travelling I got a ‘stroke’ in the car. I was then taken to a KCC health facility in Kampala. They (health workers) checked and found that I had hypertension, so that’s when it started. From that day I knew that I had hypertension. I went on receiving treatment up to this day. (26 Kyamabale_male 1-Buikwe, Rural)

Perceived Severity or Fear of the Consequences of the Disease. Patients who had mild symptoms perceived themselves to be at low risk and were likely not to seek care for their hypertension.

... here in the village as long as you are still able to walk, there is no need of you monitoring your BP because you have hope that it will subside and you will get back to normal (6 Bukumunye B_female 2). I had the disease, but because it was not very serious I kept postponing going to the health facility. (31 Lusizi_male 3-Buikwe, Urban)

Because of the low risk perceptions, such patients mainly depended on self-medication to treat symptoms or embraced a do nothing scenario. On the other hand, patients who perceived their disease to be severe especially after experiencing life-threatening symptoms were more likely to seek care promptly from bigger hospitals and avoid self-medication

... after surviving death, I no longer self-treat or cover up an illness [delay diagnosis]. (41 Ssaza_female 3-Mukono, Urban)

The Patient Beliefs about the Effectiveness of the Therapy or Recommended Advice. Some patients’ HSB and compliance were dependent on their perceptions about the effectiveness of the treatment or recommended provider advice. Effective remedies encouraged patients to return to their providers for refills, whereas patients who reported otherwise commonly reported trying out alternatives in search for better therapies.

I have managed to treat this disease (Hypertension) for the many years I have lived with

it. I have used various treatment methods. I first started with the modern method then later traditional medicine until now. However the traditional (medicine) has helped me more than the modern medicine. (8 Bulamba_Bugungu_male 1-Buikwe, Rural)

Compliance based on perceived effectiveness of therapy applied both to modern as well as herbal medicine. Those who perceived herbal medicines to be effective in relieving their symptoms were likely to report usage of such remedies.

I use the onions and the small egg plants – they help me a lot because whenever they bring them for me, I tend to feel better after using them (34 Mayugwe Ssi_female 1-Buikwe, Rural). It's very bitter and I know that hypertension can be controlled with bitter substances. When you take aloe vera, you feel well. (6 Bulamba_Bugungu_male 1-Buikwe, Rural)

Similarly, those who perceived modern medicines to be effective were likely to report modern medicine usage.

Well I went to the hospital and they diagnosed me with hypertension and they started me on the drugs and later in the process of seeking care from the modern health facility, there was someone who advised me to also use the traditional herbal medicine which I used for a short time and later realized that it was useless. So I returned to the modern health facility and they gave me the drugs to take. (P 16: Ngogwe_Kikoota_female 1-Buikwe, Rural)

A third category reported using both. This category perceived that using both modern and herbal remedies had complimentary effectiveness and resulted in better health outcomes.

For the modern medicine, they can tell you to take one tablet a day (1 × 1) of which I have already taken it in the morning at around 8.00 AM. So by evening when I feel my BP raised due to the constant movements, that is when I take that Aloe Vera - it normalizes it and I finally sleep. (2 Bugga_female 1-Buikwe, Rural)

Patients' Concerns about Adverse Effects. Patients reported that some therapies were not tolerable. They were associated with unpleasant outcomes. Some noted that adverse effects of some medicines were worse off than their hypertension. On the other hand, if the remedy was tolerable, usage was more likely. These concerns were reported for modern medicines as well as herbal medicines.

In the beginning they introduced me to start using herbal medicine; but when I started using it I realized that it had bad side effects; my hands and legs were swelling. So I stopped and remained on the modern medicine (14 Jagary_cable_female 1-Buikwe, Urban). I do not like the [modern] medicine they provide; the medicine is bitter;

others are tiny others are big. It makes 'you' weak, and dizzy; even if 'you' have a baby crying next to 'you'; it's hard to carry the baby because 'you' get weak. (29 Lusozi_female 2-Buikwe, Urban)

The Fear of Life Long Dependence on Medicine. Lifelong dependence on antihypertensive was perceived as a burden and some patients could not believe that they were ready for such a course of action. As a result, some patients reported that they swallowed drugs occasionally to try and avoid over dependency on medicine in controlling their hypertension.

3.2.3. The Socioeconomic and Structural and Cultural Environment. Besides, the healthcare and the patient related factors and several other issues were reported that influenced HSBs. We have summarized these factors under the socioeconomic and structural/cultural environment issues. More specifically, three topics were discussed: (1) education, information, and marketing of traditional medicine, (2) the patients' financial and social status, and (3) distance and transport.

(1) Education, Information, and Marketing of Traditional Medicine. Education, information, and marketing greatly influenced the use of alternative medicine for hypertension in this population. Patients reported that traditional practitioners, distributors, and proponents of herbal medicines embraced the power of sociomarketing, education, and active information sharing about their products. The most popular avenues of communication and promotion of herbal remedies included media houses such as radios and television, door-to-door information and drug distribution, and use of public address system in populated areas such as markets and assembly places.

They give us the herbal medicine that is packed in the bottles and sold on the cars that pass by advertising the herbal medicine for the people to buy. They say that their medicines heal every sickness. So I buy those Rwenzori bottles with herbal medicine and take. (23 Kikoota_female 1 – Buikwe Rural)

Another patient stated, "I would listen to him (traditional health practitioner) over the radio – that was before he went to the television; because up to date he is still on the radio and on the television. I listened to him and then I got his telephone contact and first I rang him and then I went there to see him" (11 DFI_male 1-Mukono, Urban).

On the other hand, no data was generated about efforts to use education, information, and marketing strategies to promote modern health care for hypertension.

(2) The Patient's Financial and Social Status. Financial and socioeconomic status of the patients was critical in influencing compliance and HSBs of patients with hypertension. Specifically, financial and social aspects included the ability of the patients to meet their healthcare needs, family support,

and advice from significant others. Most patients reported that hypertension was a lifetime disease that in the long run was too expensive. In fact some of them said they were already struggling with more pressing basic needs of life such as food and children school fees, which took precedence over their hypertension problems. For example, this patient narrated her story:

... its money; because you may have the money and think you will go [to the hospital] at the end of the week and then there comes a person who needs the money more than you do, for example your child calls saying mammy send me money; there is this problem; so you decide to send the money to them; so you postpone and say I will go next week. So it gets to that; you later realize you spent two months without treatment. (20 Kateete_female 1-Mukono, Rural)

On the other hand, those who had better financial standing were more likely to seek care for their hypertension.

I don't have money problem to buy medicine. I have my work which earns me money that I use to buy medicine. (1 Anthony male 1-Mukono, Urban)

In addition, patients with family members [children or other relatives] with better financial standing were reportedly supported to enhance their HSBs for hypertension.

In fact my children and my brothers' money have been spent big time – most especially my son's money has been spent so much because he wishes me to get better but all in vain. (Mayugwe_Female 2-Buikwe, Rural)

Family members also provided patients with psychosocial and moral support as well as reminding them about their scheduled appointments, drug refills, and taking the medicines. Moreover, acquaintances such as friends, community members with similar challenges, or community resource persons such as religious leaders were also reported. These particularly played a key role in providing guidance to patient on whether to use modern or traditional medicine.

(3) *Distance and Transport.* The study shows that transport, distance, and related costs influenced health seeking behaviour of patients for hypertension. Patients from far-off areas (mainly rural) incurred higher costs of transport compared to their counterparts from urban neighbourhoods and those near the health facilities. Moreover, means of transport were not always reliably available in some settings. Consequently, rural residents commonly reported transport as a key barrier to seeking care, including adhering to scheduled hospital appointments.

The only challenge I faced was lack of transport; the place was really far so it was hard to go there on foot. (P 8: 16 Kabumba_female 1-Mukono Rural)

On the other hand, urban resident either did not mention transport as a barrier or they reported ease of access to health facilities as a motivator to seek care for their hypertension.

It's because I am near the hospital so I don't spend on transport to go to Kawolo hospital. I just walk to the hospital. (P 6: 14 Jagary_cable_ female 1-Mukono, Rural)

4. Discussion

The study shows that most patients in this setting utilise varied channels of care for their hypertension. In spite of the varied health seeking behaviours (HSBs), 8 in 10 patients interviewed in this qualitative study had uncontrolled hypertension. Insufficient hypertension control is prevalent in most of Sub-Saharan Africa [13] and data suggest that these high levels of uncontrolled hypertension are attributed to non-compliance, difficulty in obtaining medication, poverty, and poor access to health care [14–16]. In addition, health system deficiencies such as lack of antihypertensive medication and long distance to facilities have been implicated in affecting HSBs and control of hypertension [13, 17, 18]. Similarly, our study found that a range of health system challenges such as inadequate services, high cost of services and medicines, frequent drug stock outs, and quality concerns were strongly attributed to noncompliance and poor HSB patterns for hypertension.

In addition, HSBs were influenced by awareness, perceived severity, perceived effectiveness of recommended intervention/therapy, concerns about adverse effects, and fear of long-term dependence on medication. The influence of awareness on HSBs for hypertension is well established [11, 32]. Being aware of one's hypertension status is critical in initiation of care and impacts on self-care management practices [32] and is associated with reduced hypertension related complications and mortalities. However, availability and access to BP monitors were reported as a challenge in this study. However, perceived disease severity was critical in determining treatment compliance and HSB. In fact some of the patients reported that it was not necessary for them to continue with treatment or go to hospital if they felt well. On the other hand, manifestation of symptoms enhanced their compliance and HSBs. With mild symptoms, they mostly self-treated with herbal or modern medicines or consulted with providers at lower level health facilities including drug shops and pharmacies, whereas patients with severe symptoms reportedly sought care from hospitals or higher level health centers. The behaviours of these patients are consistent with those of the Koreans in the stroke study whose choice of care depended on their perceived severity of symptoms. For those who perceived themselves to have mild symptoms, they used over-the-counter drugs and folk remedies or visited health care facilities such as drugstores, public health agency, herbal clinic, or hospital [33]. These findings confirm the assertion that signs and symptoms influence people to seek diagnosis and treatment. The patients contemplate about the symptoms and then decide to take appropriate actions according to their perceived degree of disease severity [33]. When they perceive that the disease is very severe, they seek more specialised care but if they feel that the disease is less severe, they embark on self-care to try and resolve the discomfort.

HSBs were also influenced by the perceived effectiveness of the recommended treatment advice and this factor applied to modern as well as herbal alternative usage. Similar findings have been reported before [34–36]. In our previous study, use of traditional medicine was associated with the perception that herbal medicines were effective [34] and in Nigeria, patients strongly considered herbal medicines as viable alternative for a cure for their hypertension [37].

Another key factor was experiencing adverse reactions. Some patients reported that they experienced terrible side effects which were regarded worse off than their hypertension. Likewise, patients in Nigeria stopped medication as a result of experienced side effects [36]. Additional studies in Nigeria [11, 36], Democratic Republic of Congo [14], and Vietnam [3] have reported similar findings.

Health seeking behaviour was to a greater extent also influenced by the socioeconomic status of patients and structural and cultural factors. Patients with better socioeconomic standing had better compliance and better health seeking behaviour. The former were more likely to afford both the direct and indirect costs of health care, whereas the later, even basic amenities of life such as food, was sometimes a problem. Osamor argued that when people are hungry, nothing else matters to them except food [36]. Similar findings related to socioeconomic status and its influence on compliance and health seeking behaviour have been reported in other settings [38, 39]. In South Africa, authors reported that patients with greater economic resources were more likely to seek treatment from private doctors and spend considerably more for all types of health services compared to their counterparts in the low socioeconomic index [39]. Likewise in Nigeria, poor socioeconomic status, low level of education, unemployment, lack of effective social support networks, unstable living conditions, long distance from treatment center, and high cost of transport negatively influenced treatment compliance and health seeking behaviours for hypertension [38].

5. Implications for Policy and Practice

These findings have significant policy and practical implications on the delivery of services for hypertension. These revolve around the need for educating both the patients and the general population on hypertension, conducting routine screening, ensuring continuity of care, adherence to treatment, patient provider relations, organisation of services to minimize multiple movements across service points, availing services, and enhancing competences of staff.

Although the multiple channels of care for hypertension increase the reach of the services, the channels make it difficult for providers to monitor treatment success rates. Nonetheless, it is unlikely that the patients' behaviour of seeking care from various channels will stop in the near future as long as the comparative advantages of the different care pathways remain. For example, self-medication is comparatively cheaper and saves a lot of patients' time. Yet, it denies the patient the opportunity to receive professional management of the disease which may result in disease complication due to poor management. Therefore, empowering lower level facilities including private drug

outlets through training, support supervision, and regulations may be harnessed to reduce risks of self-medication and enhance screening and monitoring, drug refills, and referral compliance. This empowerment would also reduce the challenges related to distance and access especially among the rural folks. On the other hand, higher level facilities should progressively be exempted from routine screening and monitoring which contributes to high patient volumes but instead be equipped and motivated to deal with referral cases in a timely manner. Meanwhile, it is also desirable to enhance the integration of traditional health practice with modern practice to bridge the gaps. Such integration would reduce bickering and situations where traditional health practitioners advice patients not to use prescribed modern medicines. Moreover, increased integration would increase interest in understanding traditional medicine and exploring its efficacy and effectiveness. With the increasing burden of chronic disease, a more sustainable financing mechanism is also warranted. A life time disease like hypertension in the long run becomes unaffordable even to the middle income category in this population. Hence, noncompliance and poor seeking behaviour and related negative health outcomes are inevitable. Exploring feasibility of instituting insurance schemes for chronic disease is recommended.

The patient related barriers have also significant implications. Jin and colleagues recommend that therapy related concerns should be addressed to contribute positively in improving patient's compliance. Prescribing medication with noninvasive route of administration and simple dosing regimens might motivate patients to be compliant [40]. Long duration of treatment period and medication side effects might compromise patient's beliefs about medication effectiveness. Therefore, healthcare providers should consider therapy related problems when designing the therapy plan and involve the patients in the process to minimize the possible therapeutic barriers [40].

6. Strengths and Limitations

This qualitative study highlights the factors influencing compliance and health seeking behaviour for hypertension among aware hypertensive patients in Mukono and Buikwe Districts in Uganda. The strength of the study lies in accruing the patients in their natural environment and learning from their experiences by using interviews in the community at the patients' homes. The patients were purposively selected to obtain a varied sample comprising of different gender, residential status, and district of residence. Limited transferability can be claimed given the small scale sized nature of the study which was conducted in only two districts in Uganda. Despite these limitations, the findings are insightful and of practical importance for programs and intervention trials aimed at feasible strategies to lower hypertension in this population.

7. Conclusions

Hypertension control among aware hypertensive patients in this setting is very low with eight in ten of patients

aware of their hypertension not controlled. These control levels are attributable to poor compliance and health seeking behaviours which in turn are influenced by a number of factors which are closely related to the health system, the patient, and the socioeconomic circumstances and the culture of using traditional medicines. Strategies are needed to improve hypertension control in this population. Such strategies should leverage the opportunities at the various levels and traditions of care and address the barriers to health seeking behaviours.

Appendix

Factors Influencing Health Seeking Behaviours of Hypertensive Patients in Mukono and Buikwe in Uganda

Qualitative Interview Guide

- (1) For how long have you had (known that you have) hypertension?
 - (2) What are your own thoughts about the cause of your hypertension?
 - (3) How did you get to know that you had hypertension?
 - (a) Probe for symptoms and diagnosis.
 - (b) How did you deal with those symptoms before you got diagnosed?
 - (i) Probe for things the patient did before he/she got actually diagnosed with hypertension (self-treatment, traditional healers, ...)
 - (c) How and when did you decide to seek treatment, what changed?
 - (i) Probe for change in symptoms, or things that might have encouraged them to actually go and seek help
 - (ii) How did they actually seek help, who helped them in making that decision where to go
 - (iii) how was the process of seeking help (meaning did you see many different people before actually seeing a doctor, how did you become diagnosed with hypertension)
 - (4) Can you explain the care and treatment process from the time you discovered that you are hypertensive?
 - (a) Probe for access to treatment and care (traditional healers, drug shops, self-medication with herbs or modern medicine, health care facilities)
 - (i) Probe for barriers and facilitators
 - (b) frequency of blood pressure monitoring and who monitors this?
 - (c) Who helps you deal with your hypertension (family, neighbours, Village health team member (VHT))
 - (d) What do they help you with?
 - (e) Adherence to treatment and defaults.
- (5) Since you became hypertensive, have you used any other methods to treat your hypertension?
 - (a) Probe for herbs or other things that they might have tried
 - (i) If yes, where do you get them from?
 - (ii) Does that interfere with your other medication (if used)
 - (iii) Why do you use herbs for your hypertension?
 - (iv) Can you explain how you came to use these products (who introduced you to these methods)
 - (6) Since you became hypertensive, have you visited or consulted a traditional healer for your hypertension?
 - (a) Probe for advice and treatment received, experience with the treatment or advice
 - (b) What influenced your decision to go to the traditional healer for your hypertension?
 - (c) How were you treated?
 - (7) Since you became hypertensive, have you been to a modern healthcare facility (health center, hospital or private clinic) for your hypertension? If yes:
 - (a) Probe for treatment and advice received, level of satisfaction
 - (b) What influenced your decision to go to a modern healthcare facility for your hypertension?
 - (c) How where you treated?
 - (8) What is your preferred healthcare service provider (modern or traditional)? Explain your preference, why do you choose one over the other or both and why?
 - (9) What recommendations would you make that can help hypertensive patients to seek care from modern healthcare facility?

We are now at the end of the interview and the questions I wanted to ask you. Are there any other issues you find important regarding this topic that we did not talk about? What?

Thank you for your valuable time and accepting to participate in this study.

Data Availability

All data relevant for this data has been included in this manuscript.

Disclosure

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflicts of Interest

The authors have no conflicts of interest to declare.

Authors' Contributions

Geoffrey Musinguzi contributed to the study design and conception, study implementation, data analysis, and interpretation of results, wrote the initial draft of the manuscript, and edited the final submitted version. Sibyl Anthierens contributed to conceptualisation, development of study tools, and interpretation of results, conducted data analysis, and participated in peer writing. Fred Nuwaha contributed to study design, conceptualisation, and training research assistants, reviewed the draft manuscript, and provided useful comments. Jean-Pierre Van Geertruyden contributed to data analysis, interpretation, and manuscript writing. Rhoda K. Wanyenze contributed to interpretation of results, manuscript writing, and critical review of the manuscript. Hilde Bastiaens contributed to conceptualisation, development of study tools, data analysis, and interpretation of results and participated in peer writing. All authors have read and approved the final manuscript.

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Research Article

Cardiovascular Risk Factors in a Suburban Community in Nigeria

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The burden of hypertension, a silent killer, continues to increase in low- and middle-income countries. This study evaluated blood pressure (BP) in healthy adults to determine their risk of developing hypertension and to reduce associated morbidity of the disease. Overall, 182 subjects aged >16 years participated in the study. Systolic (SBP) and diastolic blood pressure (DBP) was measured after a resting period using mercury sphygmomanometer. Random blood glucose (RBG) concentration was also determined. Regression models were used to determine risk of high BP with p values < 0.05 indicating statistical difference. Prehypertension was present in 36.8% population and high BP in 31% individuals with hypertensive symptoms. DBP \geq 90 mmHg was prevalent in the undiagnosed group, while diabetes comorbidity was detected in only 4 individuals. High BP or diabetes was not detected in those <20 year olds. Age > 35 years was an independent risk (likelihood ratio: 22.56, $p < 0.0001$); this increases to 26.48 ($p < 0.0001$) in the presence prediabetes and RBG > 100 mg/dl. Undiagnosed hypertension rate is high in the study area, and urgent interventions for large scale screening and management of the disease are required to reduce the burden of hypertension in Nigeria.

1. Introduction

The burden of noncommunicable diseases (NCDs) has increased in developing countries over the past decade and majority of deaths occurred in low- and middle-income countries (LMIC) [1, 2]. About 16 million people die prematurely annually from preventable NCDs, the impact of which can be lessened by reducing the risk factors associated with these diseases [3]. Diabetes and hypertension are two prevalent metabolic and leading risk factors for cardiovascular diseases, which rank the highest among the causes of mortality associated with noncommunicable diseases in Africa [3–8]. Diabetes mellitus, a chronic health condition that causes high blood sugar levels due to poor insulin production or poor utilization by the body [9], often coexists with hypertension (a systolic blood pressure \geq 140 mmHg or diastolic blood pressure \geq 90 mmHg), because they share

common disease mechanisms; one condition exacerbates the other [10–12] although this may not always be the case [13]. The global incidence of diabetes mellitus increased in the past few decades from 108 million in 1980 to 422 million in 2014 [2] and people with uncontrolled hypertension rose from 600 million in 1980 to nearly 1 billion in 2008 [3, 4]. The highest incidence of diabetes and hypertension occurring in developing countries [2, 14, 15] has been attributed to population growth, ageing, and modernization [16].

Majority of adults (>25 years of age) are affected with these conditions and are oblivious of it; this often results in complications such as cardiovascular diseases, kidney failure, stroke, blindness, and nerve damage [2, 17–19], thus increasing the risk of deaths attributable to NCDs which is projected to rise rapidly by 2030 [3, 4, 14]. Diabetes mellitus and hypertension are often asymptomatic and undetected such that many people living with these conditions are oblivious of

it [20]. Diagnosis is usually done when pathological and functional damage have progressed, thus resulting in complications and high death rates attributable to these diseases [3, 4, 6, 7, 10, 21]. Prediabetes (impaired fasting glucose and glucose tolerance) precedes the onset of diabetes, while raised blood pressure precedes hypertension; early detection and timely treatment of diabetes and hypertension are an important strategy that can be utilized in poor resource countries where NCD disease burdens are high. Studies have shown that diabetes and hypertension can be prevented or managed with drugs and lifestyle modification, thus reducing the disease burden and its sequelae [22–24]. Detection of prediabetes and prehypertension to determine persons at risk of the diseases is critical for early management and prevention of these diseases. Global prevalence of diabetes is 10% and has been on the increase in LMIC and 40% incidence of hypertension was reported in 2008 with the highest prevalence occurring in Sub-Saharan Africa; however, the prevalence varies widely across countries and regions [4, 5, 8, 25, 26]. In Nigeria, the reported prevalence of diagnosed diabetes mellitus ranges between 4.6–25% and 25–54% for hypertension, and there is a large population of undiagnosed cases [2, 11, 27–31]. In recent times, there are few studies evaluating the risks and predisposition to or early detection of hypertension and diabetes comorbidity especially in community settings in Nigeria and it has become imperative to reduce the increasing burden of cardiovascular diseases [32–34]. This study evaluates the prevalence of prehypertension and the risk of hypertension in apparently healthy adults living in semiurban communities in Nigeria where access to robust health care services is expensive and NCDs prevalence is high. The study was a cross-sectional survey which evaluated prehypertension or hypertension in healthy participants aged >16 years.

2. Methods

2.1. Study Area. The study was carried out in two suburban communities in Ota, southwest Nigeria, in April 2016 where a voluntary health survey was carried out. Ota is a populous city with a population size of over 160,000 residents. Informed consent was obtained from the participants of the study. The community leader was sought for permission and ethical approval was given by Covenant University Health Research Ethics Committee and local authority.

2.2. Study Population. The inclusion criteria for selecting the study participants were individuals who aged between 16 and 95 years, were nonpregnant, nondiabetic, or nonhypertensive, and were not under treatment for any of the conditions in the past two weeks and apparently healthy individuals who were willing to participate in the study. Persons with known chronic diseases and those who are ill and on antihypertensive or antidiabetic medication or aged ≤ 15 years were excluded from the study. Children aged < 16 years ($n = 158$), pregnant women ($n = 3$), and critically ill persons ($n = 2$) were excluded from the evaluation. The power of the study was 0.90, with 7.5% margin of error and 95% confidence limit; the minimum required sample size was 171 persons. This convenient sample size of ≤ 200 was used for the study.

2.3. Study Design. The study was a cross-sectional survey, which evaluated the presence or absence of prediabetes, or diabetes mellitus and raised blood pressure (prehypertension) or hypertension onset in healthy adults.

2.4. Clinical Assessment. Age and demography were enquired from the participants, using a mercury sphygmomanometer; BP measurements were taken thrice, in persons with high BP; after a resting period of 15 minutes, the measurement was done again by the same field worker. Blood glucose concentration was determined in a subpopulation of participants, from blood obtained from a finger prick; random blood glucose or fasting blood glucose level was estimated using Randox® Glucometer. The attending physician clerked the individuals for further enquiries about symptoms or history of diabetes mellitus or hypertension and drug use.

2.5. Evaluation. Raised blood pressure or prehypertension was taken to be systolic blood pressure (SBP) of 120–139 mmHg or diastolic blood pressure (DBP) of 80–89 mmHg. Hypertension was defined as SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg [2, 35]. Prediabetes was defined as random blood glucose (RBG) of 140–199 mg/dl or fasting blood glucose of 100–125 mg/dl. Diabetes mellitus was defined as random blood glucose level of ≥ 200 mg/dl or fasting blood glucose of ≥ 126 mg/dl [6]. Others that are not within these categories were classified as normal.

2.6. Statistical Analysis. Data are expressed as mean \pm standard deviation or proportions and were analyzed using GraphPad prism version 4 and SPSS version 16. Association between covariants and hypertension or diabetes was tested using correlation and regression models; likelihood ratio was estimated using Cox regression analysis. Chi-square test was used to compare proportions and p values of < 0.05 were taken to indicate statistical difference.

3. Results

Overall, 182 individuals who met the inclusion criteria were included in the study. There were 141 (77%) females and 16 (8.7%) participants aged ≤ 20 years in the cohort. The mean age of the participants was 41.36 years (95% confidence interval 39.26–43.46, range 16–95 years), mean systolic blood pressure (SBP) of 119.4 mmHg (95% CI 116.3–122.5, range 90–200 mmHg), and mean diastolic blood pressure (DBP) of 78.4 mmHg (95% CI 76.4–80.3, range 50–120 mmHg).

3.1. Prevalence of Prehypertension and Hypertension. Prehypertension was present in 67 (36.8%) individuals from the cohort of which 72.3% were females and 3 were aged 20–23 years. Systolic blood pressure ≥ 140 mmHg was recorded in 29 (15.9%) individuals; 23 (79.3%) of them were females; SBP of ≥ 140 mmHg was not detected in participants < 25 years old. Using standard population distribution of 50.4% females in Ota, gender adjusted prevalence of hypertension was 8.2% and 7.25% in females and males, respectively. This proportion was similar in males and females. Diastolic blood pressure ≥ 90 mmHg was present in 54 individuals (90% females). Similarly, DBP ≥ 90 mmHg was not detected in

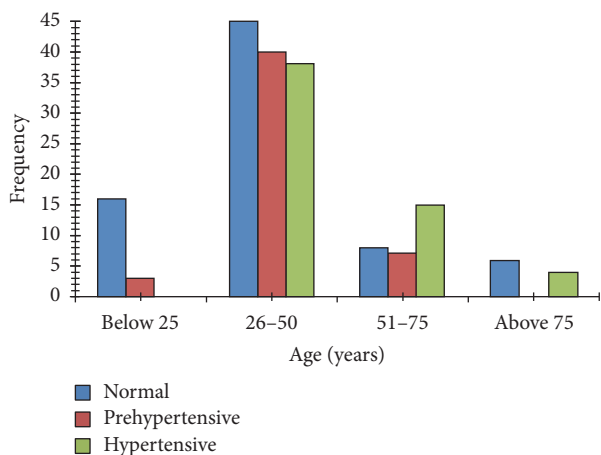


FIGURE 1: Prevalence of prehypertension and hypertension based on age in the study cohort. Prehypertension was defined as SBP 120–139 mmHg or DBP 80–90 mmHg and hypertension as SBP \geq 140 mmHg or DBP \geq 90 mmHg.

any participant <25 years. In total, 57 (31%) of the enrolled individuals had SBP \geq 140 mmHg and/or DBP \geq 90 mmHg, while 47% of them had both SBP \geq 140 and DBP \geq 90 mmHg. Figure 1 shows the age specific prevalence of prehypertension or hypertension in the cohort.

3.2. Prevalence of Prediabetes and Diabetes. Blood glucose test was done in a subpopulation of participants ($n = 79$). Random blood glucose \geq 100 mg/dl was detected in 45 participants, while prediabetes and diabetes were present in 3 and 4 individuals, respectively. None of the participants aged <20 years had prediabetes or diabetes.

3.3. Hypertension and Other Comorbidities. All 4 diabetic individuals also had hypertension comorbidity, while the 3 individuals with prediabetes had prehypertension. Few individuals in the cohort reported related symptoms such as headaches, weakness, and palpitations; this group is comprised mostly of adults older than 40 years. They were referred for appropriate medical follow-up.

3.4. Risk Assessment for Prehypertension and Hypertension. There was a significant positive correlation between prehypertension and age > 35 years (likelihood ratio 21.19, $p < 0.0001$) but not gender (likelihood ratio 0.85, $p = 0.58$) (Table 1). Likewise, there was a significant correlation between RBG and SBP ($r = 0.22$, $p = 0.04$), but not DBP ($r = 0.18$, $p = 0.10$). Prehypertension and blood sugar > 100 mg/dl showed no significant correlation ($p = 0.06$) but hypertension was significantly associated with blood sugar > 100 mg/dl (likelihood ratio 6.66, $p = 0.01$). The likelihood ratio for becoming hypertensive in the individuals aged >35 years was 22.56, $p < 0.0001$. This increases to 26.48 (odds ratio 8.72, 95% CI 3.45–22.02, $p < 0.0001$) in the presence of prediabetes. Figures 2(a) and 2(b) show the plots of age and SBP ($r = 0.48$, $p < 0.0001$) or DBP ($r = 0.36$, $p < 0.0001$), respectively, and Figure 3 shows regression plots for hypertensive and prehypertensive individuals aged <70 years with similar slope and interval in the two groups.

3.5. Symptoms. Although the study participants appeared healthy, frequently reported symptoms experienced in the past few weeks to months include palpitations, weakness, chest pain, and headaches.

4. Discussion

World Health Organization identified the African region as having the highest burden of hypertension, estimated at 46% in >25 year olds [3]. Hypertension as well as diabetes mellitus contributes significantly to the burden of noncommunicable diseases globally; about three-quarters of NCD deaths occur in low- and middle-income countries [3]. Africa bears higher disease burdens due to poor preventive and expensive health schemes and genetic susceptibilities to some diseases. In our cohort, only 31.9% individuals had blood pressure within normal range, and 91.1% had blood sugar concentration within normal range. Similar proportions of male and females in this setting presented with hypertension; other studies have reported varying gender proportions in studies carried out in Nigeria [32]. A third of our population had an undiagnosed underlying condition (31.3% were hypertensive and 5% were diabetic), and a similar proportion had prehypertension or prediabetes (36.8% and 3.4%, resp.). These rates fall within range from reported studies within and outside Nigeria [26, 28, 30, 36].

Predictions that about 75% of the world hypertensive population will emerge from developing countries by 2025 [4] is imminent. With Nigeria's population of over 200 million people, indeed there is a high population with undetected emerging burden of hypertension and reports have also shown that the highest number of people with diabetes and impaired fasting glucose lives in Africa [3, 15]. This population is at increased risk for cardiovascular disease. Hypertension and diabetes comorbidity rate of 10.5% was low in this population. Our study detected only 4 individuals with prediabetes who were also hypertensive in this cohort. It would appear that comorbidity of hypertension and diabetes or the preconditions are uncommon in this setting.

Regional variation in the prevalence of diabetes and hypertension and comorbidities due to cultural and lifestyle differences, level of awareness, and socioeconomic factors such as level of income and access to affordable health care is well established. The prevalence of diabetes in our study was very low; however, it is similar to rates of 3% in eastern Nigeria [31]. For hypertension, our study reported higher rate than another study [37], where a rate of 9.7% was diagnosed in southwest Nigeria, but similar to 37.8% rate in a clinic population reported in southern [11] and eastern Nigeria [28, 34]. Our findings are not significantly disparate with reports of other studies from Nigerian population as well as other African countries [5, 25, 32, 34, 37–41]. This finding calls for routine measures and intervention to improve case detection and diagnosis of hypertension to reduce the risk of progression to complications and associated deaths.

There was a strong correlation of age with prediabetes and prehypertension. Usually, these conditions precede the disease; although not all persons with the preconditions will develop the disease, they are implicated in developing

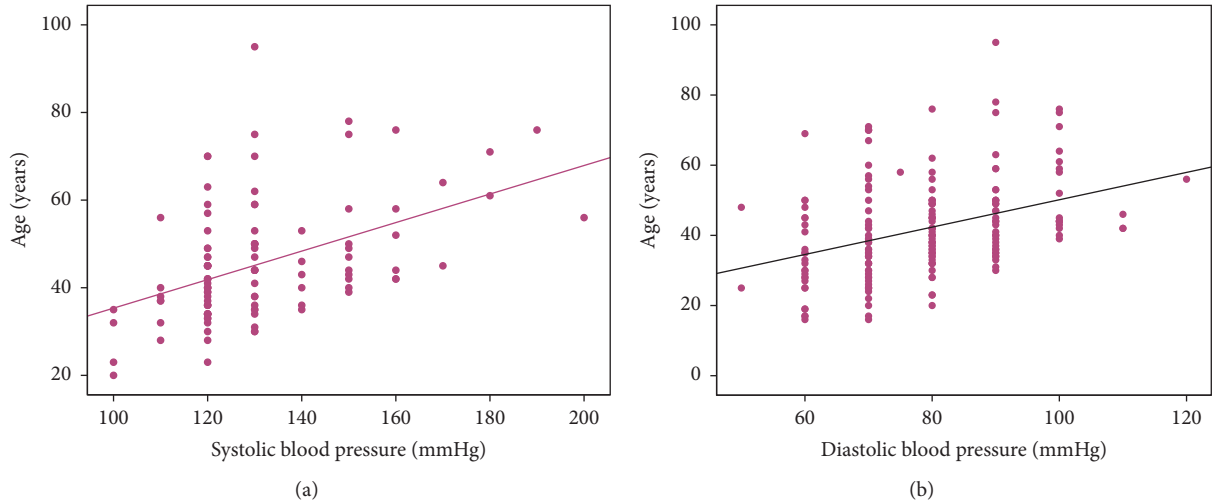


FIGURE 2: Scatter plots showing the distribution of systolic (a) ($r = 0.48, p < 0.0001$) and diastolic (b) blood pressure with age in the study cohort ($r = 0.36, p < 0.0001$).

TABLE 1: Risk assessment of prehypertension and hypertension in the cohort.

Covariants	Prehypertension odds ratio (95% CI)	Hypertension odds ratio (95% CI)	<i>p</i> value
Age (years)			
>35	4.49 (2.32–8.68)	6.34 (2.66–15.14)	<0.0001
≤35	1	1	
RBG (mg/dl)			
≥100	0.39 (0.14–1.08)*	3.32 (1.27–8.63)	0.01
<100		1	
Gender			
Male	0.85 (0.39–1.68)	0.75 (0.36–1.57)	>0.46
Female	1		

CI: confidence interval; * $p = 0.06$; RBG: random blood glucose.

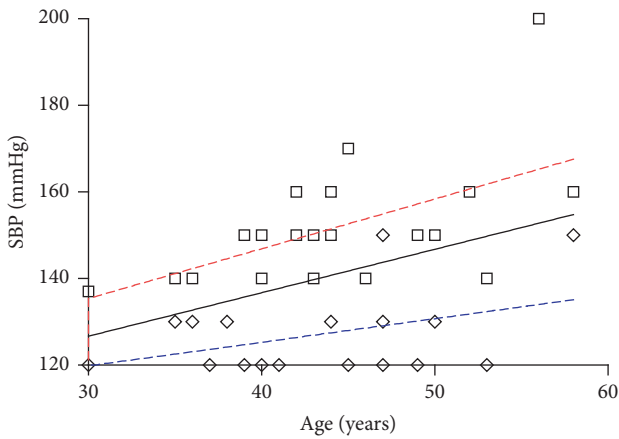


FIGURE 3: Comparison of regression plots of systolic blood pressure (SBP) and age in prehypertensive (blue dashed line), hypertensive (red dashed line), and all participants (black solid line) aged <60 years in the study cohort. Comparison of slopes: $t = 0.235, p = 0.816$; comparison of intercepts: $t = 0.002, p = 0.999$; test of coincidence, $F = 25.365, p < 0.0001$.

complications of the disease such as coronary heart disease and ischemic and hemorrhagic stroke [3, 19, 36]. Irrespective of lifestyle, screening and management of these diseases should be advocated in the adult age group. The likelihood for developing hypertension in prehypertensive population is high in the age group ≥ 35 years and consequences remain the same. NCDs caused 38 million premature deaths in 2012 and it is projected to increase to 52 million by year 2030 [3]; it is apparent that the undiagnosed population with hypertension and prehypertension of 68.1% will significantly increase soon and urgent interventions to reduce this emerging burden will help reduce morbidity and mortality caused by NCDs in LMIC. It is exigent to continue to detect the undiagnosed population and monitor trends and disease progress in affected persons for effective reduction of these public health problems.

Early detection and management of population with predisposing factors or the disease can reduce the risk of cardiovascular diseases [22–24]; however, regular screening for prehypertension or prediabetes or its knowledge as an

effective prevention measure is limited across Nigeria. In a population of hypertensives, 18% with prediabetes were detected in an African study [39] and 1.1% with prediabetes in eastern Nigeria [33]. In our population, a rate of 35.7% prehypertension was recorded in the present study. Prediabetes often precedes diabetes and the risk of progression to diabetes especially in hypertensive individuals [10, 13, 39]. Undiagnosed diabetes can progress to development of complications because these conditions are often asymptomatic. The implication of undiagnosed population in Nigeria is that if not managed, they will in the next few years contribute an increase to the already high burden of morbidity and mortality associated with NCDs in LMIC [3].

The study participants generally comprised adult farmers, traders, and low income semiurban dwellers who practice more of indigenous culture, thus a presumed healthy lifestyle. Causes of these diseases are multifactorial including older age, lifestyle, diet, and underlying genetic factors, which are modifiable by environmental and other factors for the development of either hypertension or diabetes [42]. There are limitations for the reported study; questionnaires were not given to the participants to harvest lifestyle or social status that could be assessed as covariants or determinants of the observed BP and blood sugar measurements. Our study did not also evaluate lipid profiles or other biochemical determinants that predispose one to cardiovascular diseases. Previous studies have reported obesity, dyslipidemia, sedentary lifestyle, and high alcohol consumption as some important attributable risk for the development of cardiovascular diseases in Nigeria [27, 37, 43, 44]. In this population, genetic risk factors were not determined; thus, further studies are required in this area to better predict persons at higher risks of the cardiovascular diseases and preventive strategies.

The high rate of prehypertension in this population supports predictions of future increase in prevalence of NCDs in LMICs in the future [3, 4, 14, 40]. Caution is required in the interpretation of the study outcomes, gender adjusted prevalence indicates a similar prevalence of risk of cardiovascular diseases in the area; this however is contrary to other reports of a variable prevalence of hypertension based on gender [32, 43]. Our study findings buttress the fact that there is need for urgent intervention for the emerging burden of NCDs especially when the individuals are in the prehypertensive stage. Figure 3 shows a similar pattern of regression (similar slope and intercept) in hypertensive and prehypertensive individuals although the lines appear almost parallel. If no actions are taken in this population, the imminent is bound to happen.

In conclusion, our findings indicate a low prevalence of prehypertension, prediabetes, and a high undetected population with cardiovascular diseases in the study area especially in the adult population. There were no hypertensive or diabetic persons aged <25 years, suggesting that early onset of diabetes mellitus or hypertension is not common in this region. Studies have reported effective reduction in cardiovascular diseases and outcomes of treatment in persons that were managed early [23, 24, 45]. Thus, regular screening in this age group is also advocated especially in individuals with

genetic susceptibility to the disease which can be detected early.

Conflicts of Interest

The authors hereby state that there are no conflicts of interest regarding this study.

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Review Article

A Proposed Middle-Range Theory of Nursing in Hypertension Care

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Nursing in hypertension care comprises counselling about lifestyle changes, blood pressure measurement, and being a translator for the physician. For the patient, changing lifestyle means performing self-care. As not much in the form of research and guidelines for nurses is available, a middle-range theory of nursing in hypertension care was developed to guide nurses in their practice, in order to improve the nursing of patients and design studies for investigating nursing in hypertension care. Concepts are presented related to the patient (attitude and beliefs regarding health and sickness, autonomy, personality and traits, level of perceived vulnerability, hardiness, sense of coherence, locus of control, self-efficacy, and access to social support and network) and the nursing (applying theories and models for behavioural change in the consultation and using counselling skills, patient advocacy, empowerment, professional knowledge and health education, and supporting the patient). Then the concepts related to the consultation (communication, shared decision-making, concordance, coping, adherence, and self-care) are integrated with Orem's theory of nursing. Clinical and research implications of the theory are discussed.

1. Introduction

Nursing in hypertension care has been shown to comprise counselling about lifestyle changes, blood pressure measurement, and being a translator for the physician [1]. A more detailed description of the nursing interventions is presented by Hong [2]. When a nurse is a member of a team with other healthcare professionals in the care of the hypertensive patient, a reduction in blood pressure is seen [1]. This is a result of changed lifestyle, more correct intake of medication, and more frequent returns for follow-up visits. In this context for the patient, changing lifestyle and taking medicines mean performing self-care.

Patients with hypertension during pregnancy or other severe diseases are usually taken care of within specialised care, but adult patients with hypertension are mostly managed in primary care. Preferably the care is team-based so that the patients are met in a congruent way. The team can include, besides the nurse and physician, a physiotherapist or other professionals. The members of the team have to be aware that not many patients can identify any specific symptoms that are

obviously connected with hypertension [3]; elevated blood pressure is most often detected when a patient is treated for some other ailment. The finding might surprise the patients, and then being faced with demands to perform self-care to adjust some figures on paper might be perceived as a real challenge. The nurse who sees the patient at visits to the clinic in primary care is presumed to have a health-promotional, holistic, and psychosocial approach in helping the patients to achieve blood pressure control.

Although nurses all around the world are involved in treating hypertensive patients, not many theoretical guidelines for nurses are available. There are theories of self-care and self-management of chronic illness in general, but not for hypertension specifically. A literature search found a theoretical framework for studying medication compliance in Chinese immigrants [4]. Otherwise the only papers found, with theoretical aspects, were a study that aimed to determine the effectiveness of a nurse's caring relationship according to Watson's Caring Model of blood pressure and quality of life [5], one that evaluated Orem's nursing self-care theory in hypertensive women (in Portuguese) [6], and another

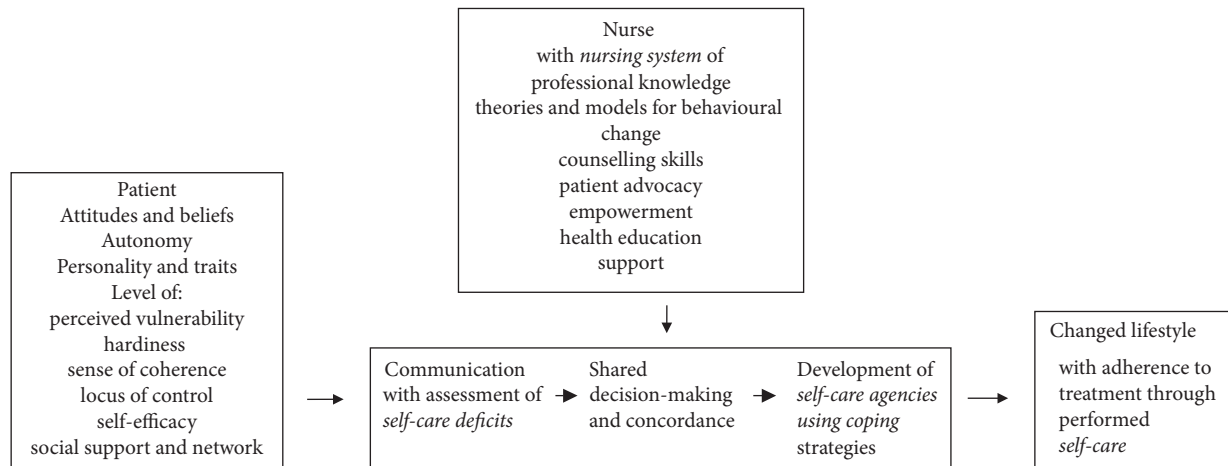


FIGURE 1: The constructed middle-range theory for nursing management of patients in hypertension care with the concepts involved in counselling about lifestyle changes and Orem's self-care deficit theory of nursing applied (shown in italics).

one that presented the middle-range theory of Attentively Embracing Story for practice implications with a client who had hypertension [7]. As these theoretical frameworks were not applied to embrace all aspects of nursing in hypertension care, a middle-range theory of nursing in hypertension care was judged to be needed to guide nurses in their practice, developing the nursing of patients and designing studies to investigate nursing in hypertension care. Former work in the development of the proposed theory has been presented [8, 9].

2. Methodology

A middle-range theory is to be developed inductively from research and practice [10] and can be combined with existing theories [11]. Theories deriving from other disciplines and practice research can also be integrated. With this background, a middle-range theory of nursing in hypertension care is proposed (Figure 1) with concepts related to the patient, nursing in hypertension care, the encounter between the patient and the nurse, the expected outcomes of this encounter, and the integration of an existing grand theory of nursing.

In the development process of the proposed theory, extensive literature search and review were conducted to find concepts that mirrored counselling on lifestyle change and taking medicines to help the patient to perform self-care. Measuring blood pressure was omitted as this is to be done in a standardised way, which is well defined in hypertension guidelines. As for nursing in general, pieces from other disciplines such as medicine, sociology, and psychology fit in well; the databases PubMed, Cinahl, PsycINFO, SocSci, and Eric were used in the literature search along with the Cochrane Library in 2001, 2005, and 2014 (Table 1). The great output from the initial searches in 2001 was diminished through a thorough review to grasp what might be relevant for nursing in hypertension care. To find any relevant paper which could give any new aspects to be taken into account

when elucidating what might be of concern for the patient and nurse in hypertension care, a variety of keywords (both MeSH terms and free text keywords) were used: adaptation, attitude, communication, compliance, coping, counselling, educational models, emotions, empowerment, health behaviour, health education, health promotion, hypertension, lifestyle, motivation, nurse-patient relations, nursing, patient self-determination, self-care, self-efficacy, and social support. The words were used separately as well as combined in the same structured way in every database. The procedure was documented to make it possible to repeat or refine the literature search.

During the review reference lists were also used to find cited original literature. While reviewing the findings from papers, books, and dissertations, a drawing was made to get an overview of relationships between the concepts and the way or order they fit in. Gradually the proposed model was formed with the concepts relevant for the patient and nurse arranged to form the model (Figure 1). The background for choosing keywords consisted of studies on nursing in hypertension care for several years while obtaining bachelors', masters', and doctoral degrees. Moreover, personal experience as an advanced nurse in primary care running a nurse-led hypertension clinic was crucial. The theory was first presented as a part of the framework of the author's thesis and some years later it was decided to rewrite the framework into a paper to be diffused among colleagues for discussion and review. Some of the concepts included are well defined but others are less well developed and defined and also not used in research with patients with hypertension. The proposed theory is work in progress and further development is needed. The theory is presented on these assumptions.

3. Definitions of Concepts

In the paper research results from each concept are presented whenever any study with hypertensive patients involved has been found regardless of the study's age. First, concepts

TABLE 1: Searches made in the different data bases during the years. The searches in 2001 started from the year of the start of the respective database.

2001		2005		2014	
Database (covering years)	Number of relevant findings	Database (covering years)	Number of relevant new findings	Database (covering years)	Number of relevant new findings
PubMed (1966–2001)	520	PubMed (2002–2005)	15	PubMed (2006–2014)	4
Cinahl (1982–2001)	326	Cinahl (2002–2005)	11	Cinahl (2006–2014)	4
PsycINFO (1967–2001)	298	PsycINFO (2002–2005)	15	PsycINFO (2006–2014)	2
SocSci (1986–2001)	147	SocSci (2002–2005)	3	SocSci (2006–2014)	2
Eric (1966–2001)	0	Eric (2002–2005)	0	Eric (2006–2014)	0

related to the patient are presented followed by the concepts related to nursing in hypertension care, concepts related to the consultation where the patient and nurse meet, the integration with Orem's self-care deficit theory, and finally the expected outcome (Figure 1).

3.1. Concepts Related to the Patient. Concepts that are related to the patients' ability, disposition, and willingness to change lifestyle and take medicines are presented here. Factors comprising attitude and beliefs regarding health and sickness, autonomy, personality and traits and level of perceived vulnerability, hardiness, sense of coherence, locus of control, self-efficacy, and access to social support and network are of importance.

3.1.1. Attitude and Beliefs regarding Health and Sickness. An attitude is a psychological tendency that is expressed by evaluating a particular entity with some degree of favour or disfavour [12] and a value can be defined as a personal belief about the worth, desirability, goodness, truth, and beauty of a particular idea or object [13]. One's concept of health is tied into one's belief systems, which means that no patient will follow instructions that the person does not believe will work or will work towards a goal not valued. For that reason the patients' values can be considered the basis for decision-making on whether to perform lifestyle change or not. Patients hold ideas about whether hypertension is a disease or not, whether the drug is necessary evil or a help, and how the drug should be taken and its effects [14], and their perceptions of the cause of hypertension, experiences of symptoms, and beliefs about the treatment can influence their self-management [15]. Assessing these attitudes and beliefs is an important first step to develop a plan of care for the patient [16].

3.1.2. Autonomy. Autonomy is defined as self-government; that is, people are autonomous to the extent to which they are able to control their own lives [17]. The hypertensive patient is facing demands to make lifestyle changes that are to be lifelong and for that reason the decision has to be autonomously made [18]; otherwise the maintenance

of the new behaviour is likely to decrease. It is therefore crucial that nurses can identify that the patient is sufficiently autonomous, which means that the patient can understand and retain the information relevant to the decision in question, believe the information, and weigh up the information to arrive at a decision.

3.1.3. Personality and Traits. A personality is a blend of two or more traits [19], which are factors that determine our conduct in many different situations and also when it comes to changing lifestyle. Traits are divided into the dimensions extraversion (active, assertive, enthusiastic), agreeableness (appreciative, forgiving, generous), conscientiousness (efficient, organised, responsible), neuroticism (anxious, tense, worrying), and openness (artistic, imaginative, insightful). States or moods are singular occurrences. Older adults, >65 years of age, who score high in conscientiousness are shown to perceive themselves as having health competence, which in turn was strongly related to health behaviours (exercise, dietary/health information, and relaxation/social support) [20]. Scoring high in conscientiousness might also promote self-control skills that can affect adherence to treatment [21]. Type A behaviour pattern, aggressively seeking to achieve more and more in less and less time, appears to increase blood pressure reactivity to external stressors in persons with mild hypertension [22].

3.1.4. Vulnerability. Vulnerability is defined in nursing literature as an externally evaluated risk (by a person outside the experience) or as an experiential state (as understood by the person herself) [23]. The individual's perceptions of self and challenges to self and of resources to withstand such challenges create the individual person's perceived vulnerability. The degree of vulnerability changes with the degree of environmental support and personal resources [24]. Psychological effects of vulnerability could give, among other things, a feeling of not belonging, helplessness, fear, anger, uncertainty, loss of control, isolation, anxiety/worry, and powerlessness. Likelihood to engage in positive action to change behaviour depends on whether the individual perceives himself as being well, chronically ill, or having an

acute illness [25]. It is concluded that a hypertensive person can be placed between well and chronically ill, which means that motivation to learn about any aspect of healthcare is based upon the acceptance of self-responsibility for health. The person does not feel vulnerable or at any risk.

3.1.5. Hardiness. The concept of hardiness was first introduced as a personality characteristic with the dimensions of commitment (active involvement in one's life activities), control (belief in the ability to influence the course of one's life events), and challenge (change is normal and growth-producing) [26]. Hardy individuals have a higher sense of commitment to self and work, perceive life change as challenging rather than threatening, and maintain a sense of control in life rather than powerlessness. Hardy persons in hypertension and RA groups are reported to be more likely to participate in patient education programmes, and this was related to better physiological functioning [27].

3.1.6. Sense of Coherence. The theory of sense of coherence is a salutogenetic model (salute = health, genesis = origin) [28]. A person with generalised resistance-resources such as money, good self-strength, cultural stability, and social support can manage to make stressors understandable, that is, have a feeling of coherence. This also involves coping strategies, that is, a plan for behaviour, social support, and cultural factors. A person with a feeling of coherence has an attitude that expresses a long-lasting and deep faith in the world's predictability and thinks there is a high likelihood that things will turn out as well as you can reasonably expect. It does not imply that one is in control but that one is involved as a participant in the processes shaping one's destiny as well as one's daily experience. It is not important whether power is in our hands or elsewhere but that the location of power is where it is legitimately supposed to be.

3.1.7. Locus of Control. As psychosocial dynamics influence health behaviour, Rotter et al. [29] developed the idea that generalised expectancies and reinforcement make a person create a sense of locus of control over the events in his life. If the effect of reinforcement is perceived as not being entirely derived from a person's own actions but the result of luck, chance, or fate, as under the control of powerful others, it is labelled a belief in external control. If the person perceives that the event originated from his own behaviour or his own characteristics, it is termed a belief in internal control. It is reported that patients with hypertension who scored high on internal control adhered to their medication had a controlled blood pressure [30].

3.1.8. Self-Efficacy. Perceived self-efficacy refers to beliefs in one's capabilities to organise and execute the courses of actions required to produce certain practical attainments [31]. If people believe they have no power to produce results, they will not attempt to make things happen [32]. Perceived self-efficacy is a uniformly good predictor for diverse forms of behaviour. Efficacy beliefs affect performance both directly and by influencing intentions. Suggested areas for research

include nonpharmacological treatment for hypertension, adherence to diet and medication regimens for lipid control, and interventions to improve exercise habits [33]. Effects of health literacy on self-efficacy and knowledge about health matters are also a factor to consider [34].

3.1.9. Social Support and Network. There is no universally accepted definition or conceptualisation of social support, but Lindsey [35] defines social support as provision of information that leads people to believe they are cared for, loved, esteemed, valued, and a member of a network of communication and mutual obligation. There are four types of social support: informational (provision of information that the person can use in coping with personal and environmental problems), appraisal (transmission of information relevant to self-evaluation), instrumental (access of the individual to behaviours that directly help in time of need), and emotional (provision of empathy and demonstration of love, trust, and caring). Social network that provides social support is defined as a group of people with whom the person has social connections, which may be formal or informal and can be described by size, density, and complexity. In studies high social network score is associated with lower systolic and diastolic blood pressure for both sexes [36]. In China it was found that social support, education, and duration of diagnosis of hypertension were significant predictors of treatment adherence [37].

3.2. Concepts Related to Nursing in Hypertension Care. Concepts of importance for the nurse when nursing patients in hypertension care are presented here. They involve applying theories and models for behavioural change in the consultation and using counselling skills, patient advocacy, empowerment, professional knowledge and health education, and supporting the patient.

3.2.1. Theories and Models for Behavioural Change. There are several theories and models developed to understand what determines behaviours. In healthcare the health belief model [38] is the most frequently used model in behaviour change. In this model goal-setting, decision-making, and social learning are integrated for making one's own decisions depending on positive or negative attitudes. Perceived susceptibility and barriers for behaviour change are included too. Other models that are useful for nurses in treating patients regarding lifestyle changes are, for example, the transtheoretical model (TTM) or stages of change model (SOC) [39] where the learner goes through a cycle from precontemplation to contemplation, preparation, and action to maintenance of new behaviour; the self-regulatory model (SRM) [40] where motivation for changing lifestyle is dependent on perceived threat; the protection motivation theory (PMT) [41] according to which judging the severity of health threats affects coping responses; or the health promotion model (HPM) [42] where perceived benefits, barriers to action, self-efficacy, interpersonal and situational influences affect behaviour change. In our own studies it was shown that nurses educated in the SOC model may have some help when using the model in counselling hypertensive patients [43].

3.2.2. Counselling Skills. The process of counselling can be defined as “the means by which one person helps another to clarify his life situation and to decide further lines of action” (p. 2) [44]. To act, the patient needs to be able to identify those things she has to do, stop doing, continue to do, and accept. Morrison and Burnard [45] suggest definitions of counselling as helping people to come to terms with a problem, enable a person to find solutions to problems, or help people to help themselves. Motivational interviewing (MI) [46] is a patient-centred goal-oriented counselling style for addressing the coercion of ambivalence about change. Using this counselling style is a way to preserve patient-centredness, empathy, and patient autonomy in the consultation. Own studies show that nurses after consultation training fulfilled more aspects of patient-centredness after the training [47] and were more focused and discussed lifestyle factors to a greater extent with their patients [48]. Furthermore effects on patients’ weight parameters, physical activity, perceived stress, and the proportion of patients who achieved blood pressure control have been demonstrated [49].

3.2.3. Patient Advocacy. An advocate is “one who pleads the cause of another” (p. 439) [50]. The concept of advocacy is linked with concepts of morality, ethics, autonomy, and patient empowerment. Gadow [51] proposes that the concept of advocacy is the philosophical foundation and ideal of nursing. The nurse is uniquely suited for fundamental and existential advocacy distinct from just providing the patient with any correct and objective information and being paternalistic. Schwartz [52] states that the advocate should inform the patient and promote informed consent, empower the patient and protect autonomy, protect the rights and interests of the patient, ensure access to available resources, support the patients, and represent the views/desires of the patients and not just their needs.

3.2.4. Empowerment. The word empower means “to authorise, to license, to impart power, to enable, and to permit” and a definition of the concept of empowerment could be “in a helping partnership it is a process of enabling people to choose to take control over and make decisions about their lives” (p. 309) [53]. Rappaport [54] views empowerment as the vehicle by which problems in living may be handled, and it suggests a sense of control over one’s life in personality, cognition, and motivation. The empowerment approach to health education seeks to increase patient autonomy and expand freedom of choice [55]. The nurse can contribute by doing assessments of patients’ psychosocial health and appraisal of health and health risks. Personal empowerment is promoted by encouraging people to identify their values, needs, goals, and the resources they have to solve problems. Awareness, freedom, choice, and responsibility are the four pillars of empowerment. Nurses’ counselling was found to contain both empowerment and nurse-centred features in a study in hypertension care, which alternated during the conversations but nurse-centred features were predominant [56].

3.2.5. Professional Knowledge. To be able to perform all the tasks that are included in nursing in hypertension care, the

nurse has to be updated in the latest guidelines for hypertension treatment, both pharmacological and nonpharmacological. Being the leader of the team [1] around the patient, as often is the case, the nurse has to have knowledge about how to value the results of the patient’s blood tests regarding, for example, blood lipids and also body measurements such as waist circumference and body mass index. The nurse also needs to be able to estimate the patient’s individual risk profile.

3.2.6. Health Education. The importance of health teaching as a part of nursing has been recognised for a long time. A professional model for teaching in nursing practice consists of four components: social service ideal (characteristics of the profession), practice environment (environment that influences the practice), client state (nurse’s view of the client), and nursing practice strategies (unique nursing interventions) [57]. This model is applicable in nursing in hypertension care as it encompasses a professional autonomy and spirit which the nurse must master as she is often managing the clinic on her own. She must also have understanding of man’s physiological and psychosocial state to make an assessment of the patient to determine the nature of teaching needed. This encompasses a holistic view. The teaching can be performed individually or in group. Hypertensive patients were interviewed about their views on a working booklet used in consultations at nurse-led clinics where the nurses had received counselling training [58]. The booklet was reported to have been read several times by some patients, but a few patients did not remember receiving it. Individual health education in primary care is reported to give lower systolic and diastolic blood pressure and body mass index and improve self-efficacy regarding medication adherence [59].

3.2.7. Support. The patient often gets social support from, for example, their next of kin and friends, but the nurse also has to support the patient regarding the specific individual lifestyle problems the patient has. Support and MI skills can also be needed to help the patients to increase their self-efficacy to succeed in changing lifestyle [46]. This could also be expressed as interpersonal transactions that include the expression of positive affect of one person towards another, the affirmation of another’s behaviours, perceptions, or expressed views, and the giving of symbolic or material aid to another person [35, 60].

3.3. Concepts Related to the Consultation and the Expected Outcome. In the consultation the patient and the nurse meet. Presented below are specific concepts related to this meeting and the expected outcome, where the nurse is communicating with the patient to reach a shared decision in concordance with the patient regarding the self-care the patient should perform. To be able to perform self-care the patient uses different coping strategies to adhere to the decided treatment.

3.3.1. Communication. Caring is an interpersonal process and builds the rapport between nurse and patient. A conceptual framework has been developed for classifying varieties of interpersonal intervention between nurse and patient

[45]. The authoritative interventions are prescriptive (to offer advice, make suggestions), informative (to offer information), and confronting (to challenge) and the facilitative ones are cathartic (to enable the release of emotion), catalytic (to “draw out”), and supportive (to encourage or validate). An interpersonally skilled person is one who can move appropriately and freely between the various categories as a means of guiding therapeutic action. All of these interventions can be found in MI [46] except the authoritative kind, which is seen as counterproductive for creating rapport with the patient. A client-centred approach means that the client himself is best able to decide how to find solutions to his problems in living [61]. All the skills of communication are also skills of counselling as listening, paraphrasing, challenging, and goal-setting [62]. Communication can be verbal or nonverbal. Interviewed hypertensive patients reported that the nurse listened and they had been guided and motivated to perform lifestyle changes after the nurses’ counselling training [58]. There were more informed thoughts about how to manage lifestyle in this group compared to the control group.

3.3.2. Shared Decision-Making and Concordance. The Swedish Health and Medical Services Act [63] states that care should be given based on respect for patients’ own decisions and their integrity. Toop from New Zealand states in a paper [64] that a patient-centred approach based on mutual participation has gained increasing support, and in the US the concept of sustained partnership between patient and clinician has been included in a definition of primary care. Mutual goal-setting is a process whereby nurse and patient collaboratively define a set of patient goals and agree on the goals to be attained. Goal-setting is an essential part of problem solving and the nursing process. Charles et al. [65] argue that the shared treatment decision-making model has four necessary characteristics: both the physician and patient are involved in the treatment decision-making process, they share information with each other, they take steps to participate in the decision-making process by expressing treatment preferences, and a treatment decision is made. Charles and contributors focus on physicians’ interaction with patients but here the principles for decision-making are generally applicable.

Through the concordance website managed by the RPSGB concordance coordinating group the new concept will begin to grow [66]. The historical background was the problem of noncompliance with medication and growing knowledge about the beliefs that people hold about their medication and about medicines in general. These beliefs decide whether the individual will comply with a prescription or not. The concept can also be extended to other treatment modalities such as behaviour change. In the consultation concordance should be based on a negotiation between equals. Concordance implies the approach of bringing patients into a full therapeutic partnership, that a patient’s decision-making preferences may change with time and circumstances, and that if the patient has relatively more authority or control in the consultation, the prescriber will have less. Moreover, the patient might choose a treatment other than that proposed by the prescriber and this is not a failure but a success of

care, and if this happens, it is no basis for rejection of the patient. In MI the word concordance is not used, but the idea of the MI spirit means that the patients are viewed as valued partners whom the counsellor wants to help to make his or her own decisions regarding health matters [46]. Shared decision-making and concordance do not overlap but rather supplement each other.

3.3.3. Coping. Coping comprises the person’s strategies to handle trying situations and demands that are appraised as taxing or exceeding the resources of the person [67], such as being diagnosed as having hypertension. A person can use strategies to handle the stress through acceptance, tolerance, medication, avoidance, and so forth or strategies to change the situation that caused the stress [68]. A vigilant coping strategy is directed to the problem in an effort to prevent or control it [67] and could mean information searching or systematic problem solving. Coping by avoidance could be jogging, relaxation, vacation, hobbies, wishful thinking, eating, drinking, smoking, using drugs or medications, or sleeping. Arora and McHorney [69] used questionnaires to study whether 2472 chronically ill (hypertension, diabetes, congestive heart failure, myocardial infarction, depression) persons preferred an active or passive role in medical decision-making. They found that patients using an active coping strategy preferred an active role in meetings with health professionals.

3.3.4. Adherence. There has been a shift through the years from using the term compliance to using adherence, though many authors still use the word compliance. Compliance has authoritative connotations, implying that the practitioner expects the patient to follow rules that are for the patient’s own good [13] or that the patient is a passive responder to the clinician’s authoritative demands [70]. Noncompliance means that the patient asserts the right of self-responsibility. Adherence can be defined as “the extent to which a person’s behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice” according to Haynes in 1979 [71]. Expectancy of internal control over health and hypertension and knowledge of the treatment regimen are significant determinants of adherence. Poor adherence to treatment can also mean that the person actually has not changed his opinion, has not understood the message completely, is not convinced about having to change behaviour to avoid illness, or has not received any help to adopt other habits [72]. Sensitivity of symptoms is generally an indicator of disease and used as a motivator and guide for treatment. Hypertension is a good example of poor sensitivity and therefore a bad motivator for treatment adaptation [40]. Regarding adherence to medication Allen [73] states that the hypertensive patient feels well and there will be no increase in perceived well-being when medication is taken, which could contribute to noncompliance. The cost of the medication [74], especially among older people [75], is an important barrier to adherence.

3.3.5. Self-Care. Self-care can be defined as activities initiated or performed by an individual, family, or community to

achieve, maintain, or promote maximum health [42]. Within the medical model, self-care has been defined as self-care in illness, compliance with therapeutic regimens, and active participation in rehabilitative activities. Self-care for health promotion requires that “clients have the knowledge and competencies that can be used to maintain and enhance health” (p. 98). A similar definition is used by Levin [76] meaning that self-care is a process where a lay person can function effectively in taking care of his or her own health promotion and prevention and disease detection and treatment. Within nursing the concept of self-management seems to encompass not only different coping strategies but also health-promotive actions, interaction with healthcare providers, adherence to treatment, monitoring health status, making care decisions, and management of the impact of the illness on health [77].

3.4. Integration with Existing Theory of Nursing. All the defined concepts related to nursing in hypertension care form the basis for nursing interventions, and the nurse makes an assessment of the patient's self-care demands in communicating with the patient to help the patient to change lifestyle, that is, to perform self-care. For that reason Orem's self-care deficit theory of nursing [78] is integrated as a natural ingredient in the proposed middle-range theory.

The self-care deficit theory of nursing consists of three parts: theory of self-care, theory of self-care deficit, and theory of nursing systems [78]. Presuppositions for the theory are that people develop and exercise intellectual and practical skills through learning and manage themselves to sustain motivation essential for continuing daily care of themselves. Self-care is an action of persons who have developed the capabilities to take care of themselves in their environmental situations. They have the agency or power to act to regulate internal and external factors that affect their own functioning and development, that is, in the interest of life, health, and well-being. The ability to perform self-care, the self-care agency as a specific power of individuals, differs depending on capabilities and circumstances related to the self-care demands and health disorders. Self-care deficit arises when capabilities for self-care, because of existing limitations, are not equal to meeting some or all of the components of their therapeutic self-care demands. In hypertension care the self-care deficit could mean that the patient has a lack of knowledge about or is not motivated to perform lifestyle changes or to start taking medicines. These deficiencies mean that the patient cannot develop appropriate self-care agency.

To meet the patient's self-care deficit, nurses produce systems of nursing actions, nursing agencies [78]. In hypertension care these agencies most often are supportive-educative to help the patient to regain his self-care. The supportive-educative system is the only system where a patient's requirements for help are confined to decision-making, behaviour control, and acquiring knowledge and skills. The nursing actions could be of long or short duration.

The concepts related to nursing (theories and models for behavioural change, counselling skills, patient advocacy, empowerment, professional knowledge, health education and support) form the nursing system in hypertension care which

the nurse brings into the encounter with the patient. The patients in turn bring certain attitudes and beliefs, a view of health, need for autonomy, their own personality and traits, perceived vulnerability, hardiness, a sense of coherence, locus of control, self-efficacy, and social support and network into the encounter. All these factors affect behaviour and thus the patients' habits. In the interaction the nurse uses appropriate parts of the nursing system to assess the patient's self-care deficits. From the interaction in the patient-centred communication, shared decision-making should emerge, with goal-setting in concordance between the patient and the nurse. From the decisions made about performing self-care the patient has to develop self-care agencies to perform behaviour change through his own coping and with assistance from nursing agencies, that is, the nurse's interventions. The desired outcome is changed lifestyle with the goal of adherence to treatment and maintenance of new behaviour. This was demonstrated in our own research in measuring hypertensive patients' exercise of self-care agency [79] where counselling training gave an increase in the patients' self-care agency scores, which was significantly correlated with increased physical activity and improved satisfaction with information about medication [80], which mirrors adherence to treatment. From Turkey it is similarly reported that hypertensive patients' educational level and social insurance situation affect the measured self-care agency score [81].

4. Clinical and Research Implications

Nursing in hypertension care has been criticised for not being fully professionally performed and for not having any structure for the counselling in the consultations [82]. Nurses could have a prominent position in the treatment of hypertensive patients, but to achieve this, the standard of the nursing needs to be enhanced. For that reason, a theory can be necessary to give a basis for the nurses to be able to develop guidelines for their own practice.

In being patient-centred in their communication, nurses must see the individual patient with his or her needs. It is then necessary for the nurse to have knowledge about what factors may affect the patient, factors that might help or be less helpful for the patient to manage to perform necessary lifestyle changes or take medicines. A patient can have the idea that living a healthy life is not for him as he is predestined because of a heavy heredity for cardiovascular diseases. His attitude is to be careless and his beliefs are that it is not worthwhile to attend to his weight. He maintains his stance to preserve his autonomy. He gives the impression of being conscientious as he is efficient and organised. Regarding his hypertension, he feels powerless (vulnerable) and thus has a low level of hardiness. He has also a low sense of coherence as he has low self-strength and feels that he is lucky if he will reach the age of fifty (external locus of control). However, he would score high on self-efficacy because when he decides to do things, he has a strong belief in being successful. He has also social support from his family and a social network that would be of help if he could be motivated to change lifestyle. This is exemplified in Table 2. In meeting patients, the experienced nurse presumably gets an impression of the

TABLE 2: A schematic description of how the nurse could make use of the proposed theory in hypertension care. All counselling sessions with patients need not follow the same order, and one concept is not used just at one particular time; for example, communication and professional knowledge are used throughout the consultation. The treatment mentioned here is lifestyle change.

Process of the consultation	Concepts related to the meeting	Concepts related to the patient	Concepts related to the nurse
Creating rapport with the patient	Communication		
Who is this person?		Personality and traits	Counselling skills
Assessing the patient's individual risk profile and telling the patient the result	Assessment of the patient's self-care deficits		Professional knowledge
What has the patient to say?		Attitudes and beliefs regarding health and sickness Sense of coherence Perceived vulnerability Hardiness	
The patient has questions		Autonomy	Health education
Discussion of pros and cons of lifestyle change where the patient reaches a decision whether to make a change or not	Shared decision-making and concordance	Locus of control	Patient advocacy Theories and models for behavioural change
The patient is willing	Development of self-care agencies using coping strategies	Self-efficacy Social support and network	Empowerment Support
Follow-up	Adherence to changed lifestyle through performed self-care		

individual patient and can report most of the statements listed in the scenario above, but the nurse would probably not be able to give a theoretical background and relate to these concepts. To be able to study and put words on what nursing in hypertension care means, a theoretical foundation is necessary.

To integrate Orem's self-care theory is particularly relevant to patient teaching with development of self-care skills [13, 32] as this is the goal for hypertensive patients and there is acceptance of the theory with its application to a variety of client populations and clinical settings (Whetstone and Reid, 1991). For many patients with hypertension it is hard to understand how the figures describing their blood pressure level are going to affect their lives. Most patients do not have symptoms that are easy to relate to the diagnosis. This means that their challenge is more demanding than those of many other patients, and it is also a big challenge for the nurse to help the patient to understand the seriousness of the figures and to motivate the patient to perform the lifestyle changes that are needed. For that reason a more detailed and applied theory is needed for the nurse in hypertension care than using Orem's grand theory alone or even a middle-range explanatory theory of self-management behaviour [83].

Intervention studies on nursing in hypertension care have been performed and show that consultation training can give

nurses a structure for the consultations [48] and that nurses can be more patient-centred in their counselling [47]. Using behavioural models as a theoretical framework has also been found to be of use [43]. Other research shows that integrating behavioural models with counselling technique as in MI [84] is helpful for healthcare providers of different professions. In doing this the provider gets a structure for the consultation and can be more effective in treating the patients. For nurses the application of a theory in hypertension care can give even deeper understanding of the patients' challenges and also of their own professional nursing actions.

Further research could be directed to different aspects of the application of the theory to clinical settings or to the theoretical relationships between the concepts. In clinical settings it would be of interest to study nurses' views on applying the theory in their practice and also hypertensive patients' views of how they perceive their treatment and their experiences of performing self-care. Intervention studies could be performed where the nursing care is based on the theory to see if this makes any difference on patient outcomes. The relationships between the concepts and a development of the different concepts need attention too. There are several questions to be answered such as what the differences between concordance and shared decision-making are, whether it is important to incorporate levels of

hardiness, sense of coherence, and locus of control in the theory, and whether it makes a difference using the word patient-centredness in defining counselling skills instead of person-centredness. According to Higgins and Moore's definitions [85], this proposed theory is predictive, that is, anticipating a particular set of outcomes, and has the components of identified and defined concepts, assumptions that clarify the basic underlying truths, a context within which the theory is placed but lacks identified relationships between and among the concepts. For that reason, views from the world of nurses interested in the development of theorising nursing in hypertension care are most valuable.

Conflicts of Interest

The author declares that there are no conflicts of interest.

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Research Article

Factors Predicting Self-Care Behaviors among Low Health Literacy Hypertensive Patients Based on Health Belief Model in Bushehr District, South of Iran

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The aim of this study was to determine the factors influencing adherence to self-care behaviors among low health literacy hypertensive patients based on health belief model. A cross-sectional study was conducted among 152 hypertensive patients with low health literacy. Patients with limited health literacy were identified by S-TOFHLA. The data were collected using H-scale for assessing self-care behaviors and, HK-LS for assessing knowledge of hypertension. A researcher-made questionnaire was applied for collecting data of health belief model constructs. Data were analyzed by SPSS version 22 with using multiple logistic regression analyses. Perceived self-efficacy was associated with all self-care behaviors except medication regimens. There was a significant association between perceived susceptibility and adherence to both low-salt diet (OR = 3.47) and nonsmoking behavior (OR = 1.10). Individuals who had more perceived severity (OR = 1.82) had significantly greater adherence to their medication regimens. Perceived benefits and barriers were not significantly associated with either type of hypertension self-care behaviors. It seems that designing and implementation of educational programs to increase self-efficacy of patients and promote their beliefs about perceived susceptibility and severity of complications may improve self-care behaviors among low health literacy hypertensive patients.

1. Introduction

Hypertension is an important worldwide public-health challenge, which can lead to very serious consequences such as cardiovascular and kidney disease [1]. According to reports, more than one in three adults worldwide suffer from high blood pressure, and this proportion increases with age [2]. Due to the high prevalence of hypertension and its serious complications, the World Health Organization (WHO) assigned the theme of World Health Day 2013 to hypertension as a “silent killer, global public-health crisis” [3]. Statistics showed an increase in the prevalence of hypertension. The number of patients with hypertension has increased from 600 million cases in 1980 to 1 billion in 2008; over 40 percent of adults were known to have hypertension [4]. Also, it was predicted that, by 2025, 1.56 billion adults will suffer from hypertension [5]. In this regard, it was reported to be 14 to 34 percent hypertensive patients in Iran [6].

Although this disease can lead to acute and debilitating complications and imposes many costs on the individual and the healthcare system, studies show that blood pressure control in hypertensive patients is not desirable, as the results of various studies all over the world suggest a high prevalence of uncontrolled blood pressure among people with hypertension [7, 8].

The most important strategy for controlling blood pressure and maintaining it in the optimal range is patient compliance with self-care behaviors [9]. The findings of a meta-analysis that examined the results of 87 studies indicated that optimal self-care in hypertensive patients could reduce systolic and diastolic blood pressure by 5 and 4.3 mmHg, respectively [10]. Self-care for people with high blood pressure includes compliance with a healthy diet (especially low salt), physical activity, nonsmoking, abstaining from alcohol, weight management, and following prescribed medications [11]. Despite the necessity of carrying

out all self-care behaviors to succeed in the management of hypertension, globally, many patients do not follow medical or lifestyle recommendations and therefore compliance with self-care behaviors in these patients is not desirable [12].

Based on evidence, self-care behaviors and blood pressure control become worse when hypertensive patients have limited health literacy [13]. Low health literacy may impact the ability to perform tasks such as understanding basic written health information or reading a prescription correctly. Low health literacy also is associated with worse chronic disease control, increased utilization of the emergency department and hospital care, and increased mortality. Lower health literacy has been associated with worse hypertension-related knowledge, lower ability to identify hypertension medications, and reduced adherence to cardiovascular medication refills. Various studies suggest that self-care behaviors are influenced by demographic variables and modifiable psychological variables [11, 14, 15]. Information about factors that affect self-care behaviors in low health literacy hypertensive patients based on theoretical framework is scarce. In this study, the HBM (Health Belief Model) was used to explain factors related to self-care behaviors of low health literacy hypertensive patients. HBM is one of the most important theories of behavior change that has been widely considered in behavioral health sciences and successfully applied in the design of health interventions. This model has emphasized the role of moderating factors (demographic, social, and structural factors) and individual perceptions (perceived sensitivity, perceived severity, perceived benefits, perceived barriers, guidance for action, and self-efficacy) in determining the likelihood of performing a behavior [16]. According to this model, a person's decision and motivation to perform a particular behavior included items such as person's perception of being at risk (perceived susceptibility) and its seriousness (perceived severity), belief in the perceived action of usefulness to reduce the risk of disease, understanding of the health benefits (perceived benefits), person's perception of the difficulties and cost of performing behaviors (perceived barrier), and moderating factors such as demographic and psychosocial variables (awareness) and people's judgments of their capabilities to execute given level of performance (self-efficacy) [17].

Therefore, the purpose of this study was to determine the factors related to self-care behaviors among low health literacy hypertensive patients based on health belief model. The results can be used as baseline data to improve self-care behaviors and blood pressure control caused by psychological factors.

2. Material and Methods

This cross-sectional study was conducted on 152 patients with limited health literacy who had been referred to the Haft-e-Tir Comprehensive Health Service Center in Bushehr city. This study was approved by the Ethics Committee of Bushehr University of Medical Sciences (IR.BPUMS.REC.1395.128). At first, patients were identified based on initial entry criteria and entered the study by convenience sampling method. Initial entry criteria for participation in the study include

having appropriate physical conditions for answering questions, age over 30 years, not having a serious complication due to hypertension (diseases such as cardiovascular disease, neuropathy, nephropathy, retinopathy, and stroke), and passing at least 6 months of definite diagnosis of the disease. The final entry criteria for the study were limited health literacy. To identify patients with limited health literacy, a Short version of Test of Functional Health Literacy in Adults (S-TOFHLA) was completed. After identifying patients with limited health literacy and before the interview, the interviewer first explained the purpose of the survey, the study participants' rights, the risk and benefit of participation, and the plan to protect the confidentiality of study participants. Further, a signed informed consent was obtained prior to the interview. Then for patients who had proclaimed their consent to participate in the study, health beliefs model and self-care behaviors questionnaire were completed. Of the 209 participants identified on the basis of initial entry criteria and convenience sampling method, 152 had limited health literacy and completed the other questionnaires.

2.1. Measurement

2.1.1. Health Literacy. Health literacy was evaluated by a shortened version of the Test of Functional Health Literacy in Adults (S-TOFHLA) that included two reading passages (36 items worth 2 points each) and 4 numeracy items (7 points each) to assess comprehension of hospital forms and labeled prescription vials that contained numerical information; this test also assesses quantitative skills and the ability to read and understand prose and documents. Possible scores on the S-TOFHLA range from 0 to 36. Based on the cut of points of the questionnaire, we categorized patients into three mutually exclusive groups: inadequate, marginal, or adequate health literacy. Scores from 0 to 55 indicate inadequate health literacy. Scores from 56 to 66 indicate marginal health literacy, and scores from 67 to 100 indicate adequate health literacy. The Persian version of the scale shows adequate internal reliability for numeracy (Cronbach's $\alpha = 0.69$) and for reading comprehension (Cronbach's $\alpha = 0.78$) [18].

2.1.2. Knowledge of Hypertension. Hypertension knowledge assessed using Hypertension Knowledge Level Scale (HK-LS). This 22-item scale prepared by Erkoc et al. [19]. HK-LS assesses respondents' knowledge in defining hypertension, lifestyle, medical treatment, drug compliance, diet, and complications of hypertension. Each item is a full sentence that is either correct or incorrect. And each item is prepared as part of a standard answer (correct, incorrect, or do not know). Zinat Motlagh et al. have validated this questionnaire in Iranian population [20]. In Persian version in the validation process, three items were excluded from the scale and the final version has 19 true/false items.

2.1.3. Health Belief Model Constructs. In order to assess the constructs of health belief model, a researcher-made questionnaire was used. Items developed for susceptibility, seriousness, benefits, barriers, and self-efficacy focused on

self-care behaviors in hypertensive patients. 39 items with 5-point Likert answers was used (9 items for perceived benefits, 7 items for perceived barriers, 9 items for perceived susceptibility, 6 items for perceived severity, and 10 items for perceived self-efficacy). For determination of content validity, the list items were distributed to judges who were faculty members and Ph.D. candidates and they were quite familiar with HBM constructs. In content validity, changing the format of questions and omitting irrelevant questions were performed. Then, mean Content Validity Index (CVI) and Content Validity Rate (CVR) of the questionnaire were calculated as 0.94 and 0.91, respectively. Reliability of the scale was calculated and Cronbach's alpha values were 0.71, 0.70, 0.70, 0.82, and 0.85 for perceived susceptibility, perceived severity, perceived barriers, perceived benefits, and perceived self-efficacy, respectively.

2.1.4. Self-Care Behavior. Self-care behaviors were determined using the hypertension self-care activity level effects (H-scale). This is a 31-item scale and was prepared by Zinat Motlagh [20]. The H-scale is designed to help primary care physicians to guide hypertensive patients who are seeking to achieve blood pressure control [21]. The H-scale examines the level of self-care by asking about the number of days per week on which an individual performs a self-care behavior. The H-scale was previously validated in Persian patients with high blood pressure [20]. The Persian version consisted of 27 items that measures the hypertension self-care activities with the following domains: medication adherence (3 items), physical activity (2 items), low-salt diet (10 items), smoking (2 items), alcohol (1 item), and weight management (9 items). The Persian version of the scale shows adequate internal consistency. Cronbach alphas were as follows: medication adherence (Cronbach's $\alpha = 0.91$), low-salt diet (Cronbach's $\alpha = 0.72$), physical activity (Cronbach's $\alpha = 0.96$), smoking (Cronbach's $\alpha = 0.91$), and weight management (Cronbach's $\alpha = 0.85$).

2.1.5. Sociodemographic Characteristics. Sociodemographic attributes, including age, sex, marital status, education level, and hypertension duration, were collected. Levels of education were divided into four categories: (1) illiterate; (2) primary school (1–5 years of schooling); (3) secondary/high schooling (6–12 years of schooling); and (4) education above high school. The number of years between the diagnosis of hypertension and point of data collection were obtained as disease duration.

2.2. Data Analysis. The data obtained from the total of 152 completed questionnaires in hypertensive patients with limited health literacy. Descriptive statistics were used to examine the characteristics of the sample. Then the participants for each of self-care behaviors were divided into two groups. First group is the low literacy patients who reported to perform self-care behaviors and second group is the low literacy patients who did not perform self-care behaviors. The multiple logistic regression analyses with forward steps likelihood ratio method was used to determine of predictive HBM constructs. All statistical analyses were performed

TABLE 1: The characteristics of respondents and descriptive findings ($n = 152$).

Variables	
Age (years)	Mean age: 56.87 years (SD = 8.70) Range: 35–80 years
Years with hypertension	Mean: 9.46 years (SD = 5.80)
Gender	Range: 1–30 years
Male	42 (27.6%)
Female	110 (72.4%)
Marital status	
Never married	3 (2%)
Married	129 (84.9%)
Divorced	20 (13.9%)
Educational level	
Illiterate	5 (3.3%)
Primary school	61 (40.1%)
Secondary/high school	77 (48.7%)
Above high school	9 (5.9%)
Family history of hypertension	
Yes	74 (48.7%)
No	78 (51.3%)
Income	
<10000000 IR-Rial	64 (42.1%)
>10000000 IR-Rial	88 (57.9%)
Medication	
Yes	149 (98%)
No	3 (2%)

using Statistical Package for Social Sciences (SPSS) version 22.0. In all tests, the level of significance was 0.05.

3. Results

3.1. Sample Characteristics. A total of 152 hypertensive patients with limited health literacy were studied. Their demographic features are shown in Table 1. The mean age of participants was 56.87 ± 8.70 ranging from 35 to 80 years (Table 1). Almost, 42 participants were male (27.6%) and 110 were female (72.4%). Participants had an average of 4.46 ± 5.8 years of diagnosed hypertension. Most of the subjects (84.9%) were married and had secondary/high school education (48.7%). More than half of patients (57.9%) reported earning more than 10 million IR-Rial ($\geq 250\$$) a month. Most of the patients (61.8%) did not work nor were employed at the time of the study. Family history of hypertension was reported in 48.7% of patients. 34.9% of patients had their systolic hypertension above 140 and diastolic blood pressure above 90 in their last care at the health center. The most important sources for receiving health information were health professionals (42.1%) and then Internet based messaging software such as Telegram and WhatsApp (17.8).

Our results revealed that only 9.2% had a proper adherence to their medication regimen, and 5.3% avoided salt both while cooking and eating. Moreover, 19.1% had physical activity on most weekdays, and 55.9% were nonsmokers.

TABLE 2: Self-care behaviors frequencies and percentages.

Self-care behavior	Number (%)
Medication adherence	14 (9.2)
Eating a low-salt diet	8 (5.3)
Physical activity	29 (19.1)
Nonsmoking	85 (55.9)
Alcohol abstinence	120 (78.9)
Weight management	41 (27.0)

21.1% were alcohol consumers, and 27% managed their weight (Table 2).

The means and standard deviations of knowledge 7.75 (SD = 2.89) and HBM constructs related to self-care behaviors were 38.60 (SD = 7.87) for self-efficacy, 16.78 (SD = 4.01) for perceived susceptibility, 13.36 (SD = 3.35) for perceived severity, 32.90 (SD = 7.07) for perceived benefits, and 14.92 (SD = 4.70) for perceived barriers.

The multiple logistic regression analysis was used to assess the predictors of adhering self-care behaviors for HBM constructs. The results of the multiple logistic regression indicated that the knowledge about hypertension and self-care was predictor of weight management (OR = 1.247) and medication regimens (OR = 1.376), that is, the patients who had known about hypertension and self-care behaviors were one time more likely to managed their weight and more likely to adhere to their medication regimen than those who had not. Self-efficacy was predictor of all self-care behaviors except no alcohol and medication regimens. Patients with greater perceived self-efficacy were more likely to have weight management (OR = 1.174) and to be nonsmokers (OR = 1.069), physically active (OR = 1.092), and to adhere to a low-salt diet (OR = 1.259) than those with lower self-efficacy. Perceived susceptibility about hypertension complications and adherence was predictor of both low-salt diet (OR = 1.139) and non-alcohol behavior (OR = 1.562). The results also revealed that individuals who had more perceived severity (OR = 1.301) had significantly greater adherence to their medication regimens compared to those who had less perceived severity. The other components of HBM (perceived benefits and barriers) were not significantly associated with either type of hypertension self-care behaviors (Table 3) and none of the HBM components predict alcohol consumption among participants.

4. Discussion

Blood pressure control in hypertensive patients was considered as a long-standing challenge. This can be more challenging, when hypertensive patients have limited health literacy. Therefore, the aim of this study was to determine the factors related to self-care behaviors as the most important way to control high blood pressure among low health literacy hypertensive patients based on health belief model. Based on findings, low health literacy hypertensive patient's adherence to self-care tasks was low in terms of healthful diet, physical activity, weight management, and medication adherence and was moderate regarding nonsmoking and alcohol abstinence.

Based on our primary results more than 90% of the participants had not a low-salt diet and they reported that they added extra salt to their food while cooking and eating. This is while the WHO suggests that every adult should consume less than 5 grams of sodium each day [22]. However, in Iran and most countries, the daily consumption of salt per person is between 9–12 grams on average [23]. This well has been confirmed that the consumption of foods containing salt accompanied by the insufficient consumption of fruits and vegetables is an important factor that lead to high blood pressure and unsuccessful management of this disease. Thus, the implementation of health interventions to reduce the consumption of salt expenditure, as well as increasing the consumption of fruits and vegetables, is a fundamental health need.

Other results show that less than one-fourth (19.1%) of the participants took part in physical activity at least 30 minutes almost every day and only 27% of the sample managed their weight. Similar to our results the other study found that 81.2% of people with arterial hypertension did not perform any kind of physical activity [24]. This is despite the fact that the WHO has suggested 30 minutes of physical activity five days a week to prevent and control high blood pressure [25]. The amount of physical activity in the study population is much lower than what has been reported by WHO. Insufficient physical activity and lack of weight management are topics that need more attention from physicians and healthcare providers but instead seems to have been ignored by them.

The prevalence of adherence to medication as the other self-care behaviors was low in study population. The overall adherence to medication in our study was 9.2% as compared to a similar study; the adherence was 48.7% [26] and, in an Iranian study by Kamran et al., 24% of the patients were adherent [14]. Probably the reason of this difference is due to limited health literacy of this study's population. It seems that adherence to medication regimen is less important for limited health literacy patients with hypertension. Therefore, the implementation of educational interventions to inform patients with hypertension about the necessity of antihypertensive drugs are essential.

We found a moderate rate of smoking and alcohol consumption in study population. Most of patients in this study avoided tobacco use (55.9%) and did not consume alcohol (78.9%). Despite the fact that smoking and alcohol consumption in Iran are not socially and culturally accepted, and, even being illegal in case of alcohol, we still see the consumption of these substances in individuals and even in patients. Multiple factors contribute to these behaviors. It is possible that participants do not associate reducing smoking and alcohol consumption as hypertension self-care behaviors. This reasoning would suggest that health providers should intervene to increase awareness of alcohol consumption and its effects on hypertension management.

The results indicated that knowledge about hypertension and self-care was significantly associated with weight management and medication regimens. This finding declares the role of knowledge as a major source and confirm a large body of research [27] that suggests knowledge about hypertension

TABLE 3: Associations between knowledge, structures, Health Belief Model, and hypertension self-care behaviors.

	Weight management OR (95% CI)	Nonalcohol OR (95% CI)	Nonsmoking OR (95% CI)	Physical activity OR (95% CI)	Low-salt diet OR (95% CI)	Medication regimens OR (95% CI)
Knowledge	1.247 (1.064–1.461)					1.376 (1.080–1.753)
Perceived susceptibility		1.139 (1.024–1.267)			1.562 (1.031–2.366)	
Perceived severity						1.301 (1.040–1.626)
Perceived self-efficacy	1.174 (1.092–1.261)		1.069 (1.044–1.149)	1.092 (1.031–1.157)	1.259 (1.053–1.505)	

and self-care can enhance the ability to cope and comply with medical regimens and disease management.

Analyzing Health Belief Model, our study found significant associations among HBM components. The findings indicated that self-efficacy is associated with adhering to low-salt diet, engaging in physical activity, not smoking, and utilizing common weight management strategies in hypertensive patients with low literacy. Our finding supports a positive relationship between self-efficacy and self-care behaviors found in previous studies [11, 28, 29]. Self-efficacy plays a crucial role in adoption of hypertension-controlling behaviors [30] and, as mentioned in other studies [31], it seems that patients with low health literacy may feel less confident in their ability to perform self-care behaviors and may have less motivation for performing self-care tasks. Consequently, increased confidence of low health literacy patients with regard to selecting appropriate behaviors seems to improve adherence to self-care tasks. Therefore, it is useful that through educational interventions, educators promote the patient's ability to perform self-care behaviors through self-efficacy strategies.

Our results showed that perceptions of susceptibility were influential for low-salt diet and nonsmoking behavior. These self-care behaviors were worse among those who had lower perception regarding the susceptibility or vulnerability to the disease process. Perceived susceptibility is one of the most important factors affecting health behaviors. Dehghani-Tafti et al. [29] introduced perceived susceptibility as a key factor in behavioral changes among diabetic patients. For the hypertensive patients with low health literacy to adopt self-care behaviors, health providers should intervene to change their beliefs to the point that they are susceptible and at risk for the complications of the disease.

Similar to other studies, medication adherence decreased with lower perception of disease severity [14, 32]. This may be due to poor health literacy that which makes the patients to have less knowledge about hypertension and its complications among these patients. Therefore, it seems that educating patients with limited health literacy about blood pressure and its complications can be effective in creating beliefs to understand the threat of high blood pressure.

In conclusion based on findings, there was minor adherence for self-care behaviors among patients with high blood pressure and low health literacy. This is due to the inadequate knowledge, perceived susceptibility, perceived severity, and perceived self-efficacy. Therefore, it is necessary that health providers improve their actions and also their communications with the patients especially patients with low health literacy to ensure a better influence on self-care behaviors. Health education based on HBM components can be useful and educational programs for these vulnerable patients should also be expanded.

Since this study was based on a convenience sample, the findings of this study may not be generalized to all Iranian hypertensive patients with low health literacy. Self-care behaviors were evaluated with self-report, so the reliability of self-rated self-care behaviors, in particular, may be subject to recall bias or memory failure. The results reported in the study were obtained from a cross-sectional survey and

no causality is established between HBM components and self-care tasks. A longitudinal study that follows the study sample and reassesses their health outcomes at a later time would help to discern the causal effects of HBM components. The S-TOFHLA, similar to other health literacy assessments, offers no indication about the respondent's communication skills, which may be equally important in determining an individual's ability to effectively navigate today's complex health care system.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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