A Randomized Controlled Trial of the Effect of a Hypertensive Educational Program on Home Blood Pressure in Hypertensive Patients at King Chulalongkorn Memorial Hospital

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Abstract

Background: The effectiveness of various non-pharmacological hypertensive therapies (including diet, exercise, Qigong, meditation) on "office" blood pressure (BP) control has been reported in previous studies. However, little is known about the effects of a hypertensive educational program on "home" BP control.

Objective: The aim of the study was to determine the effects of our unique one-day hypertensive educational program on home BP in patients with hypertension.

Methods: 66 patients (age 57.73 ± 9.04 years, 17% male) with mild to moderate hypertension were prospectively enrolled and randomly assigned to two groups: an educational intervention program and a control group. The education program of our hospital is a unique 8-hour didactic educational workshop consisting of a special high fiber and low salt recipe, meditation walk, Qigong practice, and a standard education for hypertensive patients, including basic knowledge of the disease and related complications, salt and diet control, activities, and exercise. The primary end point was the difference of home BP between baseline and that at 3 months after randomization. Home BP was defined as a mean of home BP measured by a digital self-recorder twice a day for 7-consecutive days. The secondary endpoints were the differences of body weight, waist and hip circumferences, fasting plasma glucose, and lipid profiles.

Results: A total of 31 patients in the intervention group and 33 patients in the control group completed the study at 3 months. The baseline characteristics between both groups were similar. In the intervention group, the baseline BP was 141.27 ± 13.91/83.40 ± 9.3 mmHg and at 3-months the BP was 137.46 ± 15.55/82.49 ± 10.45 mmHg. In the control group, the baseline BP was 134.83 ± 10.32/81.63 ± 10.12 mmHg and at 3-months BP was 136.31 ± 10.94/82.26 ± 9.74 mmHg. Systolic BP declined 3.81 ± 7.45 mmHg in the intervention group, but increased 1.48 ± 6.77 mmHg in the control group ($p = 0.011$). There was no significant changes of diastolic BP decline in the study group and control group ($p = 0.200$). The delta body weight, waist and hip circumferences, fasting plasma glucose, lipid profiles were not significantly different between both groups.

Conclusions: Our unique educational program with a combination between conventional and traditional/integrative means for hypertensive patients had a significant impact on home BP reduction at 3 months-follow up. Whether this means that an objective home practice and compliant quantification had incremental and/or superior effects, to a conventional educational program on home BP needs further study.

Keywords: hypertension, home blood pressure, hypertensive educational program

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Introduction

Hypertension is a major epidemic burden worldwide and in Thailand. Recently, the fourth national health survey in Thailand from 2008 to 2009 showed that the prevalence of hypertension in Thailand is about twenty percent. Hypertension can lead to severe complications, such as hypertensive cardiovascular disease, hypertensive renal

disease and atherosclerotic complications including stroke, coronary heart disease, renal insufficiency, and heart failure.

Treatment of hypertension consists of pharmacological & non-pharmacological treatment known as lifestyle modification (1). Lifestyle modification includes weight reduction that can reduce systolic blood pressure (SBP) about 5-20 mmHg for every 10 kg (2,3), DASH diet (Dietary approaches to Stop Hypertension) that can reduce SBP about 8-14 mmHg (4,5), salt restriction that can reduce SBP about 2-8 mmHg (4-6), aerobic exercise that can reduce SBP about 4-9 mmHg (7,8) and moderation of alcohol consumption that can reduce SBP about 2-4 mmHg (9).

Nowadays, there are many meditation practices that provide evidence for a blood pressure (BP) lowering effect. Qigong is an ancient Chinese healing art involving meditation, controlled breathing, and movement exercises. A meta-analysis of randomized controlled trials that compared Qigong practice with usual care resulted in Self-practiced qigong for less than 1 year being better in decreasing BP in patients with essential hypertension than in no-treatment controls, but not superior to that in active controls (10). Yoga also shows promise as a stress management tool in patients with hypertension (11). Slow & Regular breathing exercise using device-guided was also reported efficacious (12,13).

Home blood pressure monitoring (HBPM) overcomes many of the limitations of traditional office BP measurement and is both cheaper and easier to perform than ambulatory BP monitoring. Monitors that use the oscillometric method is currently available that is accurate, reliable, easy to use, and relatively inexpensive (14). The Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study evaluated prognosis with office, home, and ambulatory BP over an 11-year follow-up. Although they found that Home BP was more closely associated with the risk of cardiovascular mortality than Office BP (15), other benefits of home blood pressure monitoring were identified such as white-coat hypertension and masked hypertension. The European Society of hypertension recommended home blood pressure monitoring for all patients receiving antihypertensive medication. Also they recommended home blood pressure monitoring for research applications (16).

Recently, in our hospital, we have been conducting a unique integrative hypertensive educational program for patients with mild to moderate hypertension. Our one-day hypertensive educational program consists of basic knowledge of disease and related complications, an exercise workshop, diet for hypertension, a slow & regular breathing exercise, meditation walk, Qigong practice, mental health training, an included home practice consisting of three meals of the Thai DASH diet, exercise or walking meditation or Qigong practice at least 30 minutes per day and slow & regular breathing exercise at least 15 minutes per day.

The aim of the study was to determine the effects of a unique integrative King Chulalongkorn Memorial Hospital hypertensive educational program on home blood pressure, body weight, waist and hip circumferences, fasting plasma glucose, and lipid profiles.

Methods

Subjects

Patients were recruited from a list of patients who could attend a hypertensive educational program at King Chulalongkorn Memorial Hospital. Inclusion criteria were patients greater than 20 years old with elevated BP, unmedicated or constantly medicated with the same drugs and at the same dose throughout the study. Hypertension was defined as an average home systolic blood pressure $\geq$ 135 mmHg and/or home diastolic blood pressure $\geq$ 85 mmHg (after discontinuation of one of the antihypertensive drugs for 7 days except beta-blockers) or received more than two antihypertensive drugs. Exclusion criteria were pregnancy, acute coronary syndrome or stroke in the past 6 weeks, renal failure (serum creatinine > 3 mg/dl), history of significant liver disease, severe hypertension (defined as home BP: SBP $\geq$ 180 mmHg and/or DBP $\geq$ 110 mmHg), history of back surgery, history of CABG or PCI in the past 6 months, and unambulatory patients.

Study Design

The protocol was approved by Institutional Review Board, Faculty of Medicine, Chulalongkorn University. After informed consent, patients were asked to self-measure BP for 7 days, blood was drawn for fasting plasma glucose and lipid profiles, body weight, hip & waist circumference were measured at baseline. After baseline

measurements, patients were randomized using a block randomization into two groups: an educational intervention program and control group.

After the patient in the intervention group attended a hypertensive educational program for 4-6 weeks, they were appointed to a hospital visit and one week home blood pressure measurement.

After 12-14 weeks of the program, home BP, body weight, hip & waist circumference were again measured in both groups.

The patient in both groups were asked about compliance of antihypertensive drugs for each visit.

The primary end point was the difference of home BP between baseline and that at 3 months after randomization. Home BP was defined as a mean of home BP measured by a digital self-recorder twice a day for 7-consecutive days. The secondary endpoints were the differences of body weight, waist and hip circumferences, fasting plasma glucose, and lipid profiles

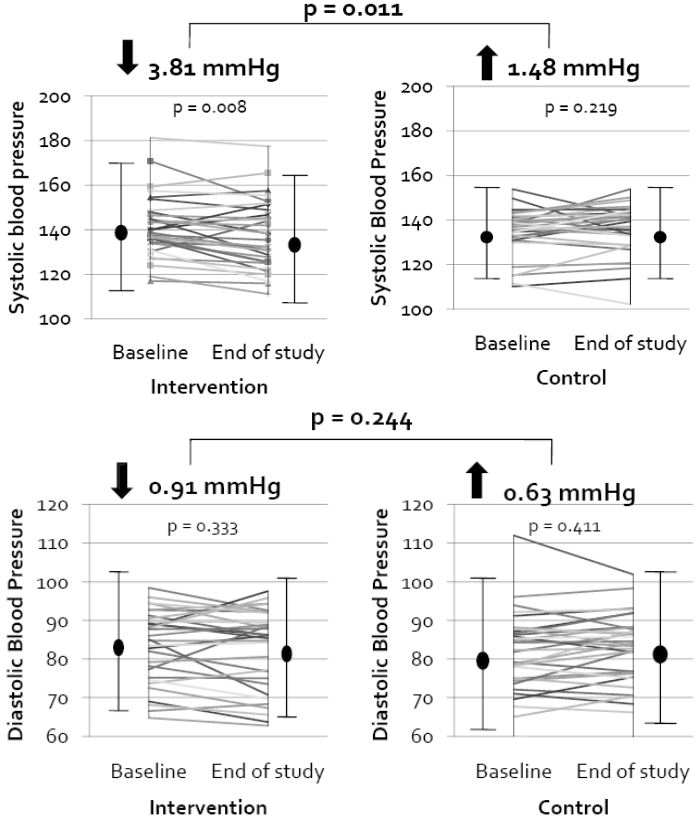
BP measurements

BP was measured at home with Microlife® Model BP 3AC1-1 PC (validated by the British Hypertension Society, European Society of Hypertension) (17) that stored all data including BP, heart rate, date and hour up to 30 measurements. Devices showed an average of 3-consecutive measurements. The devices were checked for accuracy against a mercury sphygmomanometer (14). Patients were measured twice daily in the morning & evening for seven days. Conditions of the measurements included 5 minutes of rest and 30 minutes without smoking and caffeine, seated, back supported, arm resting on the table, immobile, legs uncrossed, not talking, before drug intake, and after micturation.

Statistical analysis

Continuous variables were compared by a Student's t-test or Wilcoxon nonparametric statistics and categorical variables by chi-square statistics. We compared differences at baseline and follow-up measures between both groups using analysis of covariance (ANCOVA).

Figure 1. Difference of changes in blood pressure from baseline to end of study between the intervention & control group



Results

108 patients were assessed for eligibility. 36 patients had white-coat hypertension. One patient had severe hypertension. One patient was unambulated. 4 eligible patients declined to participate, and the remaining 66 patients underwent randomization (32 patients in the intervention group and 34 patients in the control group). In the intervention group or hypertensive educational program group, one patient was lost to follow up, with thirty one subjects in the intervention group at the end of the study. In the control group, one patient was withdrawn due to antihypertensive drug modification during the study with thirty three subjects remaining in the control group at the end of the study.

Table 1. Baseline patient characteristics by treatment group. Numbers are mean (SD) or number (percentages)

Baseline Characteristics	Intervention (n = 31)	Control (n =33)	p-value
Demographic			
Age (years)	60.35 (8.60)	55.27 (8.90)	0.024
Female	26 (83.9)	27 (82.8)	0.828
Diabetes	3 (9.7)	3 (9.1)	1.00
Dyslipidemia	10 (32.3)	13 (39.4)	0.552
Medication			
- Diuretic	5 (16.1)	5 (15.2)	0.914
- Beta blocker	9 (29.0)	9 (27.3)	0.876
- ACEI	4 (12.9)	2 (6.1)	0.419
- ARB	4 (12.9)	2 (6.1)	0.419
- Calcium channel blocker	6 (19.4)	3 (9.1)	0.296
- Aspirin	4 (12.9)	1 (3.0)	0.190
- Sulfonylurea	1 (3.2)	1 (3.0)	1.00
- Metformin	3 (9.7)	2 (6.1)	0.667
- Fibrate	3 (9.7)	1 (3.0)	0.347
- Statin	7 (22.6)	12 (36.4)	0.228
Clinical			
Systolic blood pressure (mmHg)	141.27 (13.91)	134.83 (10.32)	0.039
Diastolic blood pressure (mmHg)	83.40 (9.33)	81.63 (10.12)	0.471
Pulse rate (beats/min)	70.09 (9.98)	71.67 (8.62)	0.499
Height (cm)	158.19 (6.33)	158.48 (8.38)	0.879
Body weight (kg)	66.35 (11.97)	68.17 (14.15)	0.582
Body mass index (kg/m^2)	26.46 (4.33)	27.14 (5.36)	0.577
Waist circumference baseline (cm)	86.05 (8.63)	86.36 (9.44)	0.894
Hip circumference baseline (cm)	99.52 (7.62)	99.25 (9.56)	0.901
Laboratory measurements			
Fasting plasma glucose (mg/dl)	101.17 (15.63)	101.52 (15.24)	0.779
Cholesterol (mg/dl)	213.07 (39.15)	197.07 (35.60)	0.114
HDL (mg/dl)	55.67 (14.91)	52.04 (10.80)	0.302
Triglyceride (mg/dl)	143.90 (57.11)	120.22 (45.67)	0.092

ACEI = angiotensin converting enzyme inhibitor, ARB = angiotensin receptor blocker, HDL = high density lipoprotein

Table 2. Change in home blood pressure, body weight, hip & waist circumference

	Intervention (n = 31)	Control (n = 33)	Difference	p-value
Clinical				
SBP change (mmHg)	- 3.81 (7.45)	+1.48 (6.77)	5.29	0.011
DBP change (mmHg)	- 0.91 (5.15)	+ 0.63 (4.33)	1.54	0.244
Body weight change (kg)	- 0.46 (1.43)	- 0.53 (2.21)	0.07	0.962
BMI change (kg/m^2)	- 0.18 (0.59)	- 0.20 (0.89)	0.02	0.927
Hip circumference change (cm)	-0.44 (2.50)	0 (3.41)	0.44	0.569
Waist circumference change (cm)	-1.55 (2.86)	-0.53 (2.15)	1.02	0.114
Laboratory measurements				
Fasting plasma glucose change (mg/dl)	-0.55 (13.51)	-1.59 (13.72)	1.04	0.862
Cholesterol change (mg/dl)	-1.7 (27.10)	+7.68 (33.35)	9.38	0.078
HDL change (mg/dl)	+3.27 (9.66)	-1.00 (10.79)	4.27	0.163
Triglyceride change (mg/dl)	-13.33 (56.62)	-12.80 (45.86)	0.53	0.678

SBP = systolic blood pressure, DBP = diastolic blood pressure, BMI = body mass index, HDL = high density lipoprotein

Patient characteristics

Almost all the patients were female (83%). Baseline characteristics of the remaining subjects were age 57.73 ± 9.04 years, home BP 137.95 ± 12.49/82.47 ± 9.72 mmHg, heart rate 70.90 ± 9.29 beats/min. In our study, patients were overweight with a body mass index of 26.81 ± 4.93 kg/m^2.

Baseline characteristics were similar in both groups except for the fact that patients in the intervention group were older than those in the control group and the SBP was higher in the intervention group with the mean arterial pressure similar in both groups. Body weight, body mass index, waist and hip circumferences, fasting plasma glucose and lipid profile were similar in both groups as well (Table 1).

Clinical effects of treatment

At the end of the study, antihypertensive medications before the randomization and at the end of the study were similar. In the intervention group, the baseline BP was 141.27 ± 13.91 / 83.40 ± 9.33 mmHg and at 3-months BP was 137.46 ± 15.55 /82.49 ± 10.45 mmHg. In the control group, baseline BP was 134.83 ± 10.32/81.63 ± 10.12 mmHg and at 3-months BP was 136.31 ± 10.94/ 82.26 ± 9.74 mmHg. Systolic BP declined 3.81 ± 7.45 mmHg in the intervention group, but increased 1.48 ± 6.77 mmHg in the control group (p= 0.011). There was no significant changes of diastolic BP decline in the study group and control group (p= 0.200). Changes of body weight and hip and waist circumferences at the end of the study were similar in both groups (Table 2 and Figure1).

Discussion

The main findings of our study were that our unique hypertensive educational program had a significant effect on the reduction of systolic blood pressure but not diastolic blood pressure. This is the first study to describe a unique hypertensive educational program combining conventional and integrative measures on home blood pressure. As mentioned earlier, the previous studies used office BP and single integrative measures.

In our study using home blood pressure monitoring, we can detect white-coat hypertension in about thirty percent. This is an emphasized benefit of home blood pressure monitoring.

The effective reduction in SBP in the hypertensive educational program group may be due to self practice following the program by the subject, more patient awareness of BP using home blood pressure monitoring, and our feedback at week 4 -6 of the study. Patients' perceptions of their hypertension will thereby encourage them to be compliant with lifestyle modifications and

antihypertensive therapy. In fact, it was shown that the use of HBPM is associated with better compliance to treatment. A meta-analysis of randomized controlled trials that compared home blood pressure monitoring with usual care showed that home blood pressure monitoring resulted in better BP control than usual BP measurements (18).

Although in our study, SBP can be reduced only 3 mmHg; the data from JAMA published in 2002 showed that 2 mm of mercury reduction can reduce stroke and cardiac mortality significantly (19). This implies that our unique educational program can have a benefit in hypertensive patients. However, this needs further testing.

The limitations of our study are our inability to control co-intervention in the intervention groups such as exact antihypertensive drugs, other non-pharmacologic treatment and also contamination in the control group including other sources of knowledge such as television and radio. We have no data about the compliance practice of our subjects for adhering to what they learned from our educational program.

In conclusion, our unique educational program with a combination of conventional and traditional/integrative means for hypertensive patients had a significant impact on home BP reduction at 3 months-follow up.

Conflict of Interest

None

References

1. Papadakis MA Current Medical Diagnosis & Treatment 2004,43rd ed. New Yok: McGraw-Hill. 2004:401
2. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure. The Trials of Hypertension Prevention, phase II. The Trials of Hypertension Prevention Collaborative Research Group. Arch Intern Med 1997;157:657-67.
3. He J, Whelton PK, Appel LJ, Charleston J, Klag MJ. Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension. Hypertension 2000;35:544-9.
4. Sacks FM, Svetkey LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group. N Engl J Med 2001;344:3-10.
5. Vollmer WM, Sacks FM, Ard J, et al. Effects of diet and sodium intake on blood pressure: subgroup analysis of the DASH-sodium trial. Ann Intern Med 2001;135:1019-28.
6. Chobanian AV, Hill M. National Heart, Lung, and Blood Institute Workshop on Sodium and Blood Pressure : a critical review of current scientific evidence. Hypertension 2000 ;35:858-63.
7. Kelley GA, Kelley KS. Progressive resistance exercise and resting blood pressure : A meta-analysis of randomized controlled trials. Hypertension 2000;35:838-43.
8. Whelton SP, Chin A, Xin X, He J. Effect of aerobic exercise on blood pressure: a meta-analysis of randomized, controlled trials. Ann Intern Med 2002;136:493-503.
9. Xin X, He J, Frontini MG, Ogden LG, Motsamai OI, Whelton PK. Effects of alcohol reduction on blood pressure: a meta-analysis of randomized controlled trials. Hypertension 2001;38:1112-7.
10. Guo X, Zhou B, Nishimura T, Teramukai S, Fukushima M. Clinical effect of qigong practice on essential hypertension: a meta-analysis of randomized controlled trials. J Altern Complement Med 2008;14:27-37.
11. McCaffrey R, Ruknui P, Hatthakit U, Kasetsomboon P. The effects of yoga on hypertensive persons in Thailand. Holist Nurs Pract 2005;19:173-80.
12. Schein MH, Gavish B, Herz M, et al. Treating hypertension with a device that slows and regularises breathing: a randomised, double-blind controlled study. J Hum Hypertens 2001;15: 271-8.
13. Meles E, Giannattasio C, Failla M, Gentile G, Capra A, Mancia G. Nonpharmacologic treatment of hypertension by respiratory exercise in the home setting. Am J Hypertens 2004;17:370-4.
14. Pickering TG, Miller NH, Ogedegbe G, Krakoff RL, Artinian TN, Goff D. Call to action on use and reimbursement for home blood pressure monitoring: executive summary: a joint scientific statement from the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. Hypertension 2008;52:1-9.
15. Sega R, Facchetti R, Bombelli M, \ et al. Prognostic value of ambulatory and home blood pressures compared with office blood pressure in the general population: follow-up results from the Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study. Circulation. 2005;111:1777–83.
16. Parati G, Stergiou G, Asmar R, et al. European Society of hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. J Hypertens 2008;26:1505–1530
17. dabl Educational Trust. Sphygmomanometers for clinical use. Available at: http://www.dableducational.org/sphygmomanometers/devices_1_clinical.html#ClinTable. Accessed January 10, 2009.
18. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials. BMJ 2004;329:145
19. Whelton PK, He J, Appel LJ, et al. Primary prevention of hypertension: Clinical and public health advisory from The National High Blood Pressure Education Program. JAMA 2002;288:1882–88.

ผลของโปรแกรมการให้ความรู้เกี่ยวกับโรคความดันโลหิตสูงต่อระดับความดันโลหิตที่บ้านในผู้ป่วยโรคความดันโลหิตสูงในโรงพยาบาลจุฬาลงกรณ์, การทดลองแบบสุ่มมีกลุ่มควบคุม

วรฤทธิ์ เลิศสุวรรณเสรี, สมเกียรติ แสงวัฒนาโรจน์

บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาผลของโปรแกรมการให้ความรู้เกี่ยวกับโรคความดันโลหิตสูงต่อการควบคุมความดันโลหิตที่บ้านในผู้ป่วยโรคความดันโลหิตสูงในโรงพยาบาลจุฬาลงกรณ์

วิธีการศึกษา: ทำการศึกษาในผู้ป่วยโรคความดันโลหิตสูงระดับเล็กน้อยจนถึงปานกลาง ที่เข้าร่วมโปรแกรมการให้ความรู้เกี่ยวกับโรคความดันโลหิตสูง ซึ่งประกอบไปด้วยความรู้เกี่ยวกับโรคและภาวะแทรกซ้อนที่อาจเกิดขึ้น, การควบคุมอาหาร, การออกกำลังกาย,ฝึกปฏิบัติเดินจงกรมและชี่กง โดยผู้ป่วยจะถูกสุ่มเป็น 2 กลุ่มคือกลุ่มศึกษาและกลุ่มควบคุม เก็บข้อมูลระดับความดันโลหิตโดยใช้เครื่องวัดความดันโลหิตอัตโนมัติด้วยตนเองเป็นเวลา 1 สัปดาห์, ชั่งน้ำหนัก, รอบเอว, รอบสะโพก, ระดับน้ำตาล, โคเลสเตอรอล, ไตรกรีเซอไรด์, เอชดีแอลในเลือด ก่อนและหลังเข้าร่วมโปรแกรม 3 เดือน

ผลการศึกษา: มีผู้ป่วยกลุ่มศึกษาจำนวน 31 คน และผู้ป่วยกลุ่มควบคุมจำนวน 33 คน ข้อมูลพื้นฐานใน 2 กลุ่มไม่แตกต่างกัน ความดันโลหิตก่อนเข้าร่วมโปรแกรม 141.27 ± 13.91/83.40 ± 9.33 หลังเข้าร่วมโปรแกรม 137.46 ± 15.55/82.49 ± 10.45 มิลลิเมตรปรอท ในกลุ่มศึกษา, ความดันโลหิตก่อนเข้าร่วมโปรแกรม 134.83 ± 10.32/81.63 ± 10.12 หลังเข้าร่วมโปรแกรม 136.31 ± 10.94/82.26 ± 9.74 มิลลิเมตรปรอท ในกลุ่มควบคุม ความดันโลหิต systolic ลดลง 3.81 ± 7.45 มิลลิเมตรปรอท ในกลุ่มศึกษาแต่ ความดันโลหิต systolic เพิ่มขึ้น 1.48 ± 6.77 มิลลิเมตรปรอทในกลุ่มควบคุม (p= 0.011). ส่วนความดันโลหิต diastolic, น้ำหนัก, รอบเอว, รอบสะโพก, ระดับน้ำตาล, โคเลสเตอรอล, ไตรกรีเซอไรด์, เอชดีแอลในเลือด เปลี่ยนแปลงไม่ต่างกันในทั้ง 2 กลุ่ม