# **ORIGINAL REPORTS: PREVENTION AND TREATMENT**

# THE REPUBLIC OF GEORGIA HIGH BLOOD PRESSURE CONTROL PROGRAM

**Introduction:** 52% of adults have uncontrolled hypertension in the Republic of Georgia. We incorporated a blood pressure control program into an existing primary healthcare system in an attempt to improve the rate of blood pressure control.

**Methods:** We conducted standardized trainings of rural primary care providers—doctors and nurses—in accurate measurement of blood pressure according to the Shared Care Method of Training and Certification. Our attention was focused especially on patient management based on Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) guidelines. Antihypertensive treatment was implemented by a stepped-care approach; hydrochlorothiazide and atenolol were given to patients at follow-up visits at no cost. The treatment goal was <140/90 mm Hg based on the office blood pressure.

**Results:** A total of 251 patients with uncontrolled hypertension were enrolled in the program; 32% had stage I hypertension, 41% had stage II hypertension, and 27% had stage III, as defined by JNC VI. During the first 30 months of followup, blood pressure decreased gradually from 170/95 to 140/82 mm Hg. The rate of high blood pressure control increased progressively up to 59%.

**Conclusions:** We conclude that hypertension control can be improved in all groups of patients, even in a healthcare system with limited resources. We emphasize that Georgia or any other healthcare system should not wait for universal health care to improve high blood pressure control. It can be incorporated into whatever system exists today. (*Ethn Dis.* 2006;16[suppl 2]:S2-61–S2-65)

**Key Words:** Hypertension, Primary Care, Standardized Training

From the Union of Laboratory Diagnostic (VYB) and Department of Chronic Coronary Artery Disease (LGK), National Center of Therapy (NNK), Tbilisi, Georgia; Medical College of Wisconsin (CEG), Shared Care Research and Education Consulting, Inc. (CEG, CMG), and Center for International Health (FT), Milwaukee, Wisconsin, USA. Vakhtang Y. Barbakadze, MD, PhD; Levan G. Koblianidze, MD; Nodar N. Kipshidze, MD, PhD; Clarence E. Grim, MS, MD, PhD; Carlene M. Grim, RN, MSN; Frederick Tavill, MD

### INTRODUCTION

By now, sufficient scientific evidence has been collected to indicate that timely diagnosis and control of high blood pressure is the most cost-effective strategy to decrease rates of illness and death. Conceptually, this evidence is equally valid for both highly developed and less developed countries, but blood pressure control programs have not been tested in the latter.

Economic conditions in the Republic of Georgia allow for limited resources. The rural primary care sector, which is almost entirely dependent on government funding, has been particularly affected by these circumstances. Treatment expenses have become a barrier to high blood pressure control. Recent epidemiologic studies have shown that the prevalence of hypertension in the 40- to 70-year-old age group in Georgia was 52% and that 82% of the hypertensive patients do not go to healthcare centers and clinical institutions.1 Antihypertensive and other medications may be had in Georgian drug stores without a prescription; therefore, most patients take non-recommended antihypertensive medications in ineffective doses and without physician supervision.

The objective of our project was to evaluate the effectiveness of a standard-

ized and inexpensive blood pressure control program in present-day Georgian conditions. We used a standardized diagnosis, treatment, and monitoring algorithm in the existing primary healthcare system.

## **METHODS**

All hypertensive persons detected during the rapid survey method in Dusheti, which is  $\approx 60$  km from Tbilisi (the capital of Georgia), were invited to participate in the Hypertension Control Program. The rest of the patients were selected from persons registered as hypertensives at the polyclinic.

We conducted standardized training of rural primary care providers-five doctors and five nurses-in accurate measurement of blood pressure according to the Shared Care Method of Training and Certification<sup>2</sup> by using videos, triple-stethoscope testing, and written examination; all video and written materials were translated into Georgian. At the trainings, we focused especially on accurate blood pressure measurement<sup>3</sup> and patient management according to the American Heart Association (AHA) recommendations. We discussed with the healthcare teams in detail the results of the major hypertension trials. We also adopted the recommendations of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) reports and emphasized patient and family education and compliance.

Address correspondence and reprint requests to Vakhtang Y. Barbakadze, MD, PhD; National Centre of Therapy; 3, Chachava Str, 0159; Tbilisi, Georgia; 995-99-563326; 995-32-522686; vakhtangb@ hotmail.com

Antihypertensive treatment was implemented by a stepped-care approach. Hydrochlorothiazide (HCTZ) was used as the first-step medication. If an initial systolic blood pressure (BP) was 140-159 mm Hg, 12.5 mg HCTZ was prescribed, with subsequent titration up to 25 mg. If the goal BP was not achieved, then a beta-blocker (atenolol) was added incrementally at 25 mg, 50 mg, 75 mg, and 100 mg. HCTZ and atenolol were provided to patients free of charge. If the goal BP was not achieved after taking the maximal doses of these two medications (HCTZ 50 mg and atenolol 200 mg), an angiotensin-converting enzyme inhibitor or long-acting calcium channel blocker was prescribed; these drugs were purchased by the patients themselves if they could afford to do so. If initial systolic BP was 160-179 mm Hg, starting dose of HCTZ was 25 mg. If an initial BP was >180 mm Hg, 25 mg of HCTZ and 25 mg of atenolol were prescribed together. Blood pressure was measured three times by a doctor and a nurse during each visit, according to AHA recommendations. The mean values of the six separate systolic and six separate diastolic blood pressure measurements were used as that visit's blood pressure.

To evaluate the effectiveness of the intervention, patient visits were scheduled weekly. If BP was not at goal at the visit and the patient had not missed medications (according to self-report), the dose of medication was increased or another medicine was added using the stepped-care approach mentioned above. After achieving goal BP, the last regimen was not changed, and the next visit was scheduled for a month later. After three consecutive months of BP control, the visit interval was increased to two months. A BP <140/90 mm Hg was the treatment goal.

Patients who missed three visits were dropped from the program so others could be entered. Site visits to the rural area were made by Vakhtang Y. Barbakadze and Levan G. Koblianidze twice per month. During each site visit, data were collected, patient records were reviewed, difficult cases and problems were discussed with the physician-nurse teams, and specific treatment recommendations were given. At each site visit, updates in hypertension trials were discussed with local staff. Annual trainings/workshops were carried out by the US team with emphases in accurate measurement of BP and contemporary management of hypertension according to new trials, AHA recommendations and JNC reports. Each healthcare team was provided with a mercury manometer, double stethoscopes, and three standard-size cuffs.

## **Statistics**

Data from the monitoring forms of patients participating in the Hypertension Control Program were entered into a Microsoft Office Excel database. The results were analyzed by antihypertensive treatment regimens in the different groups by age, sex, initial BP, and major co-morbid conditions. Data analysis was performed with the MINITAB 11.12 for Windows statistical program. Materials were statistically evaluated by basic statistics methods, which are the following: descriptive statistics, one sample t test (confidence intervals for the mean), and ANOVA method one-way analysis of variance were used. A P value <0.05 was considered significant.

# RESULTS

We enrolled 251 patients with uncontrolled hypertension from Dusheti into the Hypertension Control Program from May 2000 through December 2003. Their baseline data were as follows: 73% (n=184) of participants were women, and 27% (n=67) were men; mean age was 58±8 (standard deviation) years (range 36–88); mean weight, was 76±13 (42–125) kg; average duration of hypertension was 7 years; initial systolic pressure was

Table 1. Changes of the average systolic pressure by Analysis of Variance (ANOVA) over the 30 months of the program

Level	Mean	StDev
Initial	170.01	19.61
Month 1	168.50	15.63
Month 2	167.50	17.77
Month 3	159.30	17.99
Month 6	159.45	18.80
Month 9	156.23	20.60
Month 12	153.73	20.41
Month 15	149.41	21.57
Month 18	148.66	20.46
Month 21	144.05	16.29
Month 24	143.95	13.50
Month 27	141.21	14.41
Month 30	140.31	10.23

Pooled StDev = 18.64P = 0.000.

170 $\pm$ 20 (138–253) mm Hg; initial diastolic pressure was 95 $\pm$ 10 (65–143) mm Hg; initial pulse was 75 $\pm$ 8 (52–97) beats per min. Thirty-two percent (n=81) of patients had stage I hypertension, 41% (n=102) had stage II hypertension, and 27% (n=68) had stage III hypertension, as defined by JNC VI. Isolated systolic hypertension was detected in 25% (n=63), and isolated diastolic hypertension was detected in only one case.

We did not exclude any patients with hypertension from the study; 27% (68/251) of the participants had other concomitant diseases (co-morbid conditions). The most frequent concomitant diseases were congestive heart failure (15%, n=37), stroke (6%, n=15) (including recurrent stroke in three patients), myocardial infarction (5%, n=12), diabetes (4%, n=10), peripheral vascular diseases (4%, n=10), renal diseases (2%, n=5), cancer (n=4), tuberculosis (n=2), and goiter (n=1). Before enrollment, 88% (n=221) of the patients had used different antihypertensive medications from time to time. However, only five persons were taking a thiazide diuretic or beta blocker.

Changes in systolic pressure during follow-up are given in Table 1. Systolic



Fig 1. Hypertension control rate of continuing patients. The figure represents patients who continued participation over the duration of the high blood pressure control program. The y-axis shows the percentage of patients who had goal systolic (<140 mm Hg) and diastolic (<90 mm Hg) blood pressure at subsequent visits

pressure decreased gradually, and after 30 months mean systolic pressure decreased from 170 to 140 mm Hg. Diastolic pressure decreased gradually as well from 95 to 82 mm Hg. After 30 months of active treatment, the rate of high blood pressure control increased to 59% (Figure 1). BP control increased progressively in all patients who took part in the program (including those who dropped out for different reasons: emigration, death, etc). Even with the intention to treat,  $\approx 40\%$  of all participants had controlled blood pressure (Figure 2). During 3.5 years, 92 patients discontinued participation in the



Fig 2. Hypertension control rate by intention to treat analysis. The figure represents all patients who took part in the hypertension control program (including those who dropped out because of different reasons: emigration, death, etc). The y-axis shows the percentage of patients who had goal systolic (<140 mm Hg) and diastolic (<90 mm Hg) blood pressure at subsequent visits

program because of different reasons. Twenty-one refused after the first visit. Migration out of the rural area was the most frequent cause of discontinuation (n=23). Those who dropped out appeared to be similar to those who stayed in the program; average follow-up period was 255 days. Their initial BP (172/95 mm Hg) did not differ from the mean BP of the sample. Of the 30 persons followed for  $\geq 15$  months, average systolic pressure was 151 mm Hg (95% confidence interval [CI] 143.30-159.57 mm Hg) and average diastolic pressure was 88 mm Hg (95% CI 84.03-91.38 mm Hg). Decrease of blood pressure was 19/7 mm Hg. The BP of those who stayed in the program decreased by a mean of 21/9 mm Hg.

A total of 18 patients died during 30 months of follow-up. Ten patients (5 women and 5 men) died of cardiovascular causes; among them, 5 patients had stage II hypertension and 5 had stage III. The average followup period was 189 days, and between the first and the last visits systolic BP decreased by 9 mm Hg and diastolic BP decreased by 4 mm Hg. Eight patients died during the first 12 months, and two died in the 15th month. Two patients had only one visit. Three patients had undergone 2 months of treatment before they died.

Causes of death included myocardial infarction (n=5), sudden death (n=2), stroke (n=2), and congestive heart failure (n=1). In both cases of stroke, initial BP level was high (188/ 110 mm Hg and 220/118 mm Hg).

We separated patients by sex, age, and BP level (Table 2). Systolic as well as diastolic BP decreased after 30 months of follow-up in all groups. Antihypertensive treatment was effective in all patients, regardless of initial BP level. The higher the initial BP, the greater the reduction achieved.

HCTZ was used in all patients starting from the first visit until the end of the survey. The average initial dose of HCTZ was 25 mg, and at the

	BASELINE*			AFTER 30 MONTHS OF FOLLOW -UP				
GROUPS	Number of Patients	Systolic BP	Diastolic BP	Systolic BP	Change of Systolic BP	Diastolic BP	Change of Diastolic BP	% Under Control**
Total	251	170	95	140	-30	82	-13	59
Male	67	173	98	136	-37	80	-18	66
Female	184	169	94	141	-28	83	-11	56
Age < 60	123	166	95	139	-27	82	-13	64
$Age \ge 60$	128	174	96	142	-32	83	-13	53
I Stage of hypertension	81	152	89	138	-14	81	-8	68
II Stage of hypertension (JNC VI)	102	168	93	139	-29	81	-12	63
III Stage of hypertension (JNC VI)	68	194	106	145	-49	85	-21	41
Isolated systolic hypertension	63	158	84	139	-19	83	-1	74
Systolic BP $\geq 200$	25	213	112	150	-63	87	-25	20
Diastolic BP ≥110	27	201	112	152	-49	88	-24	17
Patients with major co-morbid conditions §	68	172	98	148	-24	86	-12	30

Table 2.	The average blood	pressure and the	percent of	patients under	control in various subgroup	s

\* Baseline data are for all patients before the treatment; Data shown in the category "After 30 months of follow-up" are for those who continued participation at 30 months of follow-up.

\*\* Blood pressure less than 140/90 mm Hg was considered as hypertension control.

\$ Major co-morbid conditions: congestive heart failure, stroke, myocardial infarction, diabetes, peripheral vascular diseases, renal diseases.

end of follow-up it increased to 35 mg. Use of atenolol was gradually increased from an average daily dose of 48 mg in 33% of patients and reached 60 mg in 93% of patients at the end of follow-up.

Our program was provided with medications purchased in the United States in bulk batches of 1000 tablets of HCTZ and atenolol. The price of one tablet was approximately US \$0.01. The price of delivered medications was approximately US \$8 per year per patient.

# DISCUSSION

The average decrease in systolic BP in our program was 30 mm Hg and in diastolic BP was 13 mm Hg. Taking into account the experience in other studies, one would expect that in our study stroke would be reduced by  $\geq$ 40%, myocardial infarction by 20%–25%, congestive heart failure by  $\geq$ 50%<sup>4</sup> and all-cause death by  $\geq$ 20%.<sup>5</sup> Expected effect of participation in the Georgian program should be much more than would be expected in the United States because most patients had been untreated or treated incorrectly. As our data have shown (Table 2), our program was effective in all groups: in younger patients as well as in older persons, in men and women, at all stages of hypertension. It was also effective in patients with isolated systolic hypertension or with initial critical systolic ( $\geq$ 200 mm Hg) or diastolic ( $\geq$ 110 mm Hg) BP and in patients with different co-morbid conditions.

We purchased 1000 50-mg tablets of HCTZ and atenolol for this program from the United States. The price of a 50-mg tablet was approximately US \$0.01. The cost of treatment was  $\approx$ 15 GEL (Georgia currency equivalent to US \$8) per year per patient. So the price of sufficient HCTZ and atenolol for 4 days is equal to the price of a cigarette in the local market.

Some factors affected BP control. Almost everyone knew they had hypertension and had access to a home BP measuring device. The major problem was to convince the healthcare system and patients that success could be achieved with limited resources.

We had some problems at the start of the program. Patients were not used to taking medications daily; physicians/ patients were concerned about using thiazide diuretics and beta blockers rather than "modern drugs"; other practitioners in the area discouraged attendance.

Our program had several limitations: it was not randomized, the three-year dropout rate was 20%, and we were not able to monitor laboratory tests or perform other diagnostic tests.

We conclude that hypertension control can be improved with limited resources by conducting an active antihypertensive treatment program in the Georgian primary healthcare system. Active treatment based on standardized methods, continuous training of healthcare providers, supplying patients with free drugs, and close follow-up were efficacious in all groups of patients, irrespective of age, sex, initial level of blood pressure and co-morbid conditions.

If hypertension is not brought under control, the state will continue to lose the main work force from premature death from cardiovascular and renal disease. Treating the population with these disabilities will be a major economic burden. Because of the rapid and profound benefits of this inexpensive program, we believe that the healthcare system in Georgia, or any other country,

#### REPUBLIC OF GEORGIA BLOOD PRESSURE PROGRAM - Barbakadze et al

should not wait for a universal primary healthcare system to implement this program. We have conducted an effective high BP control program in Dusheti, a rural area of Georgia. Now the program is being replicated in two other Georgian regions: Mtskheta-Mtianeti and Shida Kartli in a larger population.

#### **ACKNOWLEDGMENTS**

The Hypertension Control Program in Georgia was approved by the Health Department of the Region of Mtskheta-Mtianeti as part of the contract with the American International Health Alliance (AIHA) and the United States Agency for International Development (USAID). This program has been made possible by support from the USAID, AIHA and the Center for International Health (CIH), under contract number UCCGEO04PPTRMIMT and by support from Shared Care Research and Education Consulting Inc., Milwaukee, WI, USA. The opinions expressed here are those of the authors and do not necessarily reflect the views of AIHA, USAID, or CIH.

#### References

- Kipshidze NN, Barbakadze VY, Tataradze R, et al. Hypertension Control Status in Georgian Urban and Rural Population. *The Materials of the 27th World Congress of Internal Medicine*. Granada, Spain. September 26 – October 1, 2004; Volume 204, Supplement 1:41. Available at: http://www.doima.es/rce.
- Grim CM, Grim CE. A curriculum for the training and certification of blood pressure measurement for health care providers. *Can J Cardiol*, 1995;11:38H–42H.
- Perloff D, Grim CM, Flack J, et al. Recommendations for human blood pressure determination by sphygmomanometry. *Circulation*. 1993;88:2460–2470.
- Neal B, MacMahon S, Chapman N. Effects of ACE inhibitors, calcium antagonists, and other blood-pressure-lowering drugs: results of prospectively designed overviews of randomized trials. Blood Pressure Lowering Treatment Trialists' Collaboration. *Lancet.* 2000;356: 1955–1964.

 Hypertension Detection and Follow-up Program Cooperative Group. Five-year findings of the hypertension detection and follow-up program. I. Reduction in mortality of persons with high blood pressure, including mild hypertension. *JAMA*. 1979;242(23):2562–2571.

#### AUTHOR CONTRIBUTIONS

- Design concept of study: Barbakadze, Kipshidze, C.E. Grim, C.M. Grim, Tavill
- Acquisition of data: Barbakadze, Koblianidze, C.E. Grim, C.M. Grim, Tavill
- Data analysis interpretation: Barbakadze, Koblianidze, Kipshidze, C.E. Grim, Tavill
- Manuscript draft: Barbakadze, Koblianidze, Kipshidze, C.E. Grim, C.M. Grim, Tavill
- Statistical expertise: Barbakadze, C.E. Grim, Tavill
- Acquisition of funding: Kipshidze, C.E. Grim, Tavill
- Administrative, technical, or material assistance: Barbakadze, Koblianidze, Kipshidze, C.M. Grim, Tavill
- Supervision: Kipshidze, C.E. Grim, C.M. Grim, Tavill